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➤ Discovery Laboratories, Inc. is a biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies (SRT) for respiratory diseases. Surfactants are compositions produced naturally in the lungs and are essential for breathing. Discovery's technology produces an engineered version of natural human lung surfactant that is designed to closely mimic the essential properties of human lung surfactant. Discovery believes that through its technology, pulmonary surfactants have the potential, for the first time, to be developed into a series of respiratory therapies for critical care and other hospitalized patients where there are few or no approved therapies available.

Discovery recently completed two Phase 3 clinical trials of Surfaxin®, the Company's lead product, for the treatment of Respiratory Distress Syndrome in premature infants and is preparing to file new drug applications with the United States Food and Drug Administration and other worldwide regulatory authorities. Our Surfactant Replacement Therapy is currently in a Phase 2 clinical trial for Acute Respiratory Distress Syndrome in adults, as well as a Phase 3 and Phase 2 clinical trial for Meconium Aspiration Syndrome in full-term infants. Using aerosolized formulations of our Surfactant Replacement Therapy, we are preparing to initiate a Phase 2 trial for severe asthma (development name DSC-104) and a Phase 2 trial for Respiratory Dysfunction in premature infants.

SRT for Respiratory Medicine

	Preclinical	Phase I	Phase II	Phase III	NDA
Neonatal Intensive Care Unit					
RDS-premature infants	Surfaxin				
MAS(Tx) full-term infants	Surfaxin lavage				
MAS(Px) full-term infants	Surfaxin bolus lavage				
Respiratory Dysfunction	Aerosolized formulation with nCPAP*				
Critical Care & Hospital					
ARDS-adults	Surfactant segmental lung wash				
Asthma	DSC-104*				
Acute Lung Injury Px	Aerosolized				
COPD	Aerosolized				
Ambulatory					
Otitis Media					
Rhinitis/Sinusitis					

*Anticipated status as of second half 2004.

For the most updated information on Discovery's progress, please visit the company's web site at www.discoverylabs.com or contact us directly at: 215-340-4699.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

**/X/ Annual Report pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

For the fiscal year ended December 31, 2003

**// Transition report pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

For the transition period from _____ to _____

Commission file number 0-26422

DISCOVERY LABORATORIES, INC.

(Exact name of registrant as specified in its charter)

DELAWARE

(State or other jurisdiction of
incorporation or organization)

94-3171943

(I.R.S. Employer
Identification No.)

350 SOUTH MAIN STREET, SUITE 307, DOYLESTOWN, PENNSYLVANIA 18901

(Address of principal executive offices)

(Zip Code)

(215) 340-4699

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class

None

Name of each exchange
on which registered

None

Securities registered pursuant to Section 12(g) of the Act:

**Common Stock, \$.001 par value and,
Preferred Stock Purchase Rights**

(Title of class)

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES X NO

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. / /

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). YES /X/ NO / /

The aggregate market value of shares of voting and non-voting common equity held by non-affiliates of the registrant computed using the closing price of common equity as reported on NASDAQ SmallCap Market under the symbol DSCO on June 30, 2003, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$285 million. For the purposes of determining this amount only, the registrant has defined affiliates to include: (a) the executive officers named in Part III of this Annual Report on Form 10-K; (b) all directors of the registrant; and (c) each shareholder that has informed the registrant by February 29, 2004 that it is the beneficial owner of 10% or more of the outstanding shares of common stock of the registrant.

As of February 29, 2004, 43,697,370 shares of the registrant's common stock were outstanding.

Portions of the information required by Items 10 through 13 of Part III of this Annual Report on Form 10-K are incorporated by reference to the extent described herein from our definitive proxy statement, which is expected to be filed by us with the Commission within 120 days after the close of our 2003 fiscal year.

Unless the context otherwise requires, all references to “we,” “us,” “our,” and the “Company” include Discovery Laboratories, Inc. (“Discovery”), and its wholly-owned, presently inactive subsidiary, Acute Therapeutics, Inc.

FORWARD LOOKING STATEMENTS

The statements set forth under Item 1: “Business” and elsewhere in this report, including in Item 7: “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Risks Related to Our Business” and those incorporated by reference herein which are not historical, including, without limitation, statements concerning our research and development programs and clinical trials, the possibility of submitting regulatory filings for our products under development, the seeking of collaboration arrangements with pharmaceutical companies or others to develop, manufacture and market products, the research and development of particular compounds and technologies and the period of time for which our existing resources will enable us to fund our operations, constitute “Forward Looking Statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance. Forward-looking statements are subject to many risks and uncertainties which could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements.

Examples of the risks and uncertainties include, but are not limited to: the inherent risks and uncertainties in developing products of the type we are developing; possible changes in our financial condition; the progress of our research and development (including the results of clinical trials being conducted by us and the risk that our lead product candidate, Surfaxin[®], will not prove to be safe or useful for the treatment of certain indications); clinical trials require adequate supplies of drug substance and drug product which may be difficult or uneconomical to procure or manufacture; timely obtaining sufficient patient enrollment in our clinical trials; the impact of development of competing therapies and/or technologies by other companies; our ability to obtain additional required financing to fund our research programs; our ability to enter into agreements with collaborators and the failure of collaborators to perform under their agreements with us; the progress of FDA approvals in connection with the conduct of our clinical trials and the marketing of our products; the additional costs and delays which may result from requirements imposed by the FDA in connection with obtaining the required approvals; and the other risks and certainties detailed in Item 7: “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Risks Related to Our Business,” and in the documents incorporated by reference in this report.

Except to the extent required by applicable laws or rules, we do not undertake to update any forward-looking statements or to publicly announce revisions to any of the forward-looking statements, whether as a result of new information, future events or otherwise.

PART I

ITEM 1. BUSINESS.

COMPANY SUMMARY

We are a biopharmaceutical company developing our proprietary humanized lung surfactant technology as Surfactant Replacement Therapies for respiratory diseases. Surfactants are compositions produced naturally in the lungs and are essential to the lungs' ability to absorb oxygen and to maintain proper airflow through the respiratory system. The absence or depletion of surfactants is involved in a number of respiratory diseases.

Our technology produces an engineered version of natural human lung surfactant that is designed to closely mimic the essential properties of human lung surfactant. We believe that our surfactant technology provides the opportunity, for the first time, for pulmonary surfactants to be developed into a series of respiratory therapies for critical care and other hospitalized patients where there are few or no approved therapies available.

We recently completed two Phase 3 clinical trials of Surfaxin[®], our lead product, for the treatment of Respiratory Distress Syndrome in premature infants and are preparing to file new drug applications with the United States Food and Drug Administration and other regulatory authorities in the rest of the world.

Our Surfactant Replacement Therapy is also in a Phase 2 clinical trial for the treatment of Acute Respiratory Distress Syndrome in adults, as well as in a Phase 3 and Phase 2 clinical trial for the treatment of Meconium Aspiration Syndrome in full-term infants. In addition, we recently completed a successful Phase 1b clinical trial in healthy volunteers and mild asthmatics and are currently preparing to initiate a follow-on Phase 2 clinical trial evaluating the safety, tolerability and efficacy of our humanized lung surfactant, delivered as an inhaled aerosol (development name DSC-104), to treat patients with asthma.

Presently, we are evaluating the development of other aerosolized formulations of our humanized surfactant to potentially treat premature infants in Neonatal Intensive Care Units in hospitals that are suffering from Respiratory Dysfunction. We are also evaluating aerosolized formulations of our humanized surfactant to potentially treat Acute Lung Injury, chronic obstructive pulmonary disease (often referred to as COPD, which is a chronic condition of the lung that prevents enough oxygen from reaching the blood), rhinitis, sinusitis (infection of the sinuses), sleep apnea and otitis media (inner ear infection).

We are presently implementing a long-term commercial strategy which includes manufacturing for the production of our humanized surfactant drug products to meet anticipated clinical and commercial needs, and sales and marketing capabilities to execute the launch of Surfaxin, if approved, in the U.S. and Europe.

SURFACTANT TECHNOLOGY

Our humanized surfactant technology was invented at The Scripps Research Institute and was exclusively licensed to Johnson & Johnson which, together with its wholly-owned subsidiary, Ortho Pharmaceutical Corporation, developed it further. We acquired the exclusive worldwide sublicense to the technology in October 1996.

Surfactants are protein and lipid (fat) compositions that are produced naturally in the lungs and are critical to all air-breathing mammals. They cover the entire alveolar surface, or air sacs, of the lungs and the terminal conducting airways which lead to the air sacs. Surfactants facilitate respiration by continually modifying the surface tension of the fluid normally present within the alveoli, or air sacs, that line the inside of the lungs. In the absence of sufficient surfactant or should the surfactant degrade, these air sacs tend to collapse, and, as a result, the lungs do not absorb sufficient oxygen. In addition to lowering alveolar surface-tension, surfactants play other important roles in human respiration including, but not limited to, lowering the surface tension of the conducting airways and maintaining airflow and airway patency (keeping the airways open and expanded). Human surfactants include four known surfactant proteins, A, B, C and D. It has been established, through numerous studies, that surfactant protein B (SP-B) is essential for respiratory function.

Presently, the FDA has approved surfactants as replacement therapy only for Respiratory Distress Syndrome in premature infants, a condition in which infants are born too soon and thus have an insufficient amount of their own natural surfactant. The most commonly used of these approved replacement surfactants are derived from pig and cow lungs. Though they are clinically effective, they have drawbacks and cannot readily be scaled or developed to treat broader populations for Respiratory Distress Syndrome in premature infants and other respiratory diseases. There is presently only one approved synthetic surfactant available, however, this product does not contain surfactant proteins, is not widely used and is not actively marketed by its manufacturer.

Animal-derived surfactant products are prepared using a chemical extraction process from minced cow and pig lung. Because of the animal-sourced materials and the chemical extraction processes, there can potentially be significant variation in production lots and, consequently, product quality specifications must be broad. In addition, the protein levels of these animal-derived surfactants are inherently lower than the protein levels of native human surfactant. The production costs of these animal-derived surfactants are high, relative to other analogous pharmaceutical products, generation of large quantities is severely limited, and these products cannot readily be reformulated for aerosol delivery to the lungs.

Our humanized surfactant product candidates, including Surfaxin, are engineered versions of natural human lung surfactant and contain a humanized peptide, sinapultide. Sinapultide is a 21 amino acid protein-like substance that is designed to closely mimic the essential attributes of human surfactant protein B (SP-B), the surfactant protein that is most important for the proper functioning of the respiratory system. Our products have the ability to be precisely formulated, either as a liquid instillate, aerosolized liquid or dry powder, to address various medical indications.

We believe that our engineered humanized surfactant can be manufactured in sufficient quantities, in more exact and consistent pharmaceutical grade quality, less expensively than the animal-derived surfactants and has no potential to cause adverse immunological responses in young and older adults, all important attributes for our products to potentially meet significant unmet medical needs. In addition, we believe that our engineered humanized surfactants might possess other pharmaceutical benefits not currently found with the animal surfactants such as longer shelf-life, reduced number of administrations to the patient's lungs and elimination of the risk of animal-borne diseases including the brain-wasting bovine spongiform encephalopathy (commonly called "mad-cow disease").

Aerosolized Surfactant Formulations

Many respiratory diseases are associated with an inflammatory event that causes surfactant dysfunction and a loss of patency of the conducting airways. Scientific data support the premise that the therapeutic use of surfactants in aerosol form has the ability to reestablish airway patency, improve pulmonary mechanics and act as an anti-inflammatory. Surfactant normally prevents moisture from accumulating in the airways' most narrow sections and thereby maintains the patency of the conducting airways.

We are currently developing aerosolized formulations of our humanized surfactant to potentially treat patients who could benefit from surfactant-based therapy to improve lung function and maintain proper airflow through the respiratory system. Our aerosol development program is initially focused on surfactant-based therapy for hospitalized patients suffering from severe acute asthma or Acute Lung Injury. In addition, we believe that scientific rationale supports the development of aerosolized formulations of our humanized surfactant to potentially treat COPD, sinusitis, rhinitis, sleep apnea and otitis media (inner ear infection).

The aerosolized formulations of our humanized surfactant that we are currently developing are intended to be administered using various aerosol devices and, to date, we have achieved the following important development objectives:

- full retention of the surface-tension lowering properties of a functioning surfactant necessary to restore lung function and maintain patency of the conducting airways;
- full retention of the surfactant composition upon aerosolization;
- drug particle size suitable for deposition in the deep-lungs;
- delivery rates to achieve therapeutic dosages in a reasonable time period; and
- reproducible aerosol output and minimal waste of surfactant dose.

SURFACTANT THERAPY FOR RESPIRATORY MEDICINE

Products for the Neonatal Intensive Care Unit

Surfaxin for Respiratory Distress Syndrome in Premature Infants

Respiratory Distress Syndrome is a condition in which premature infants are born with an insufficient amount of their own natural surfactant. Premature infants born prior to 32 weeks gestation have not fully developed their own natural lung surfactant and therefore need treatment to sustain life. This condition often results in the need for the infant to undergo surfactant replacement therapy or mechanical ventilation. Respiratory Distress Syndrome is experienced in approximately half of the babies born between 28 and 32 weeks gestational age. The incidence of Respiratory Distress Syndrome approaches 100% in babies born less than 26 weeks gestational age. Surfaxin is the first humanized, protein B-based agent that mimics the surface-active properties of human surfactant. To treat premature infants suffering from Respiratory Distress Syndrome, surfactants, including Surfaxin, are delivered in a liquid form and injected through an endotracheal tube (a tube inserted into the infant's mouth and down the trachea).

During 2003, we completed and announced successful results from both a landmark, pivotal Phase 3 clinical trial and a supportive Phase 3 clinical trial of Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants. We intend to use the results from these trials to form the basis for a new drug application (NDA) for approval in the United States and to support other regulatory applications in the rest of the world. Filing of the NDA is anticipated in April 2004.

The pivotal Phase 3 trial enrolled 1,294 patients and was designed as a multinational, multicenter, randomized, masked, controlled, prophylaxis, event-driven, superiority trial to demonstrate the safety and efficacy of Surfaxin over Exosurf[®], an approved, non-protein containing synthetic surfactant. Survanta[®], a cow-derived surfactant and the leading surfactant used in the United States, served as a reference arm in the trial. Key trial results were assessed by an independent adjudication committee comprised of leading neonatologists and pediatric radiologists. This committee provided a consistent and standardized method for assessing critical efficacy data in the trial. An independent Data Safety Monitoring Board (DSMB) was responsible for monitoring the overall safety of the trial and no major safety issues were identified. In accordance with the study's trial design, we continue to conduct six and twelve month clinical follow-up on all enrolled patients.

The supportive, multinational Phase 3 clinical trial enrolled 252 patients and was designed as a non-inferiority trial comparing Surfaxin to Curosurf[®], a porcine (pig) derived surfactant and the leading surfactant used in Europe. This trial demonstrated the overall safety and non-inferiority of Surfaxin to Curosurf. In accordance with the study's trial design, we continue to conduct six and twelve month clinical follow-up on all enrolled patients.

There are over 3,000,000 premature infants born annually worldwide. More than 850,000 of these premature infants are considered "very low birth weight" infants (less than 1,250 grams), of which, approximately 700,000 are considered at significant risk for Respiratory Distress Syndrome. Due to limitations associated with the animal-derived surfactant products that are currently approved to

treat Respiratory Distress Syndrome in premature infants, access to such therapy is mainly limited to the approximately 150,000 very low birth weight infants born in the United States and Western Europe. This results in hundreds of thousands of premature infants born in the world each year who need, but do not receive, effective surfactant replacement therapy.

The FDA has granted us Orphan Drug Designation for Surfaxin for Respiratory Distress Syndrome. Orphan drugs are pharmaceutical products that are intended to treat diseases affecting fewer than 200,000 patients in the United States. The Office of Orphan Product Development of the FDA grants certain advantages to the sponsors of orphan drugs including, but not limited to, seven years of market exclusivity upon approval of the drug, certain tax incentives for clinical research and grants to fund testing of the drug. We are also seeking Orphan Product designation from the European Medicines Evaluation Agency (the European Union's regulatory approval agency that is similar to the FDA) for Surfaxin for indications of Respiratory Distress Syndrome in premature infants.

Aerosolized Surfactant Replacement Therapy for Respiratory Dysfunction in Premature Infants

Serious respiratory problems are some of the most prevalent medical issues facing premature infants in Neonatal Intensive Care Units. On top of the approximately 700,000 premature infants born annually worldwide at risk for Respiratory Distress Syndrome, there are another approximately 1 million premature infants, 300,000 of which are in the US and Europe, born annually at risk for a range of other respiratory problems associated with surfactant dysfunction. These infants are usually at a birth weight greater than 1,250 grams and neonatologists generally try to avoid mechanically ventilating these patients because doing so requires intubation (the highly invasive process of inserting a breathing tube down the patient's trachea). This reluctance is due to the perceived risks by many neonatologists regarding the intubation of these larger babies, such as the risk of trauma and the need of paralytic agents and sedation. As a result, many neonatologists will only intubate in cases of severe respiratory disease, where the benefits clearly outweigh the risks. We believe that there is growing recognition by the neonatal medical community for the potential utility of a non-invasive method of delivering surfactant replacement therapy to treat premature infants suffering from Respiratory Dysfunctions beyond Respiratory Distress Syndrome.

We are presently evaluating the development of aerosolized formulations of our humanized surfactant administered via a nasal continuous positive airway pressure or similar device as a non-invasive means to potentially treat premature infants in Neonatal Intensive Care Units suffering from Respiratory Dysfunction. We are preparing to initiate a Phase 2 dose escalation clinical trial that we anticipate conducting at several leading neonatal clinics in the U.S. in the second half of 2004.

Surfaxin for Meconium Aspiration Syndrome in Full-Term Infants

Meconium Aspiration Syndrome (often referred to as MAS) is an inflammatory condition in which full-term infants are born with meconium in their lungs that depletes the natural surfactant in their lungs. Meconium is a baby's first bowel movement in its mother's womb and, when inhaled, Meconium Aspiration Syndrome can occur. Meconium Aspiration Syndrome can be

life-threatening as a result of the failure of the lungs to absorb sufficient oxygen. There are no approved therapies for this condition and the standard of care principally consists of mechanical ventilation. Surfaxin has been shown to not only remove inflammatory and infectious infiltrates from the lungs when using our proprietary lavage (or “lung wash”) but to also replenish the vital surfactant levels in the babies’ lungs.

Surfaxin is being evaluated in a Phase 3 clinical trial for the treatment of Meconium Aspiration Syndrome in full-term infants. To our knowledge, Surfaxin is the only product being developed worldwide to treat this syndrome. The trial is designed for the enrollment of up to 200 infants at medical centers throughout the United States to compare our proprietary Surfaxin lavage to the current standard of care.

We also have initiated a Phase 2 clinical trial of our proprietary Surfaxin lavage in up to 60 full-term infants for use as a prophylactic or early treatment for patients who are at risk of developing Meconium Aspiration Syndrome but have not shown symptoms of compromised respiratory function. Surfaxin is administered as a liquid bolus through an endotracheal tube as well as by our proprietary lavage (“lung-wash”) technique. We believe an effective and affordable surfactant prophylactic therapy could significantly lower the risk to meconium-stained infants of chronic respiratory conditions and reduce the need for costly and invasive mechanical ventilation.

We presently anticipate both of the trials for the treatment of Meconium Aspiration Syndrome to be completed in 2005. See Item 7: “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Risks Related to our Business - The clinical trial and regulatory approval process for our products is expensive and time consuming, and the outcome is uncertain.”

There are presently no drug therapies approved for the treatment of Meconium Aspiration Syndrome in full-term infants. An estimated 60,000 infants are born in the United States and Europe that require treatment for MAS, however, a significantly greater number of infants are born worldwide each year at risk. The FDA has granted us Fast-Track Status and Orphan Drug Designation for Surfaxin in this indication. We have also received Orphan Product designation of Surfaxin for this indication from the European Medicines Evaluation Agency.

Products for the Critical Care Unit and other Hospital Settings

Surfaxin for Acute Respiratory Distress Syndrome in Adults

Acute Respiratory Distress Syndrome (often referred to as ARDS) is a life-threatening disorder for which no approved therapies exist anywhere in the world. It is characterized by an excess of fluid in the lungs and decreased oxygen levels in the patient. One prominent characteristic of this disorder is the destruction of surfactants naturally present in lung tissue. The conditions are caused by illnesses including pneumonia and septic shock (a toxic condition caused by infection) and events such as smoke inhalation, near drowning, industrial accidents and other traumas.

We are presently conducting a Phase 2 open-label, controlled, multi-center clinical trial of Surfaxin for the treatment of adults with Acute Respiratory Distress Syndrome. Approximately 110 patients will receive high concentrations of Surfaxin which will be administered via a proprietary sequential lavage technique, or lung wash, where Surfaxin is delivered through a bronchoscope to each of the 19 segments of the lung. The procedure is intended to cleanse and remove inflammatory substances and debris from the lungs, while leaving sufficient amounts of Surfaxin behind to help re-establish the lungs' capacity to absorb oxygen. The objective is to restore functional surfactant levels and to allow critically ill patients to be removed from mechanical ventilation sooner.

We have completed Part A of this Phase 2 trial, a dose escalation safety and tolerability study in 22 patients in four groups (of up to six patients per group). In consultation with the trial's Independent Safety Review Committee, comprised of three prominent pulmonologists, we determined that the Part A portion of the trial procedure is generally safe and tolerable and that it was appropriate for us to proceed onto the larger safety and efficacy portion of the trial.

The last part of this Phase 2 trial, Part B, is designed to evaluate safety and efficacy of Surfaxin in direct comparison to the current standard of care and will be conducted at approximately 40 centers throughout North America. The primary endpoint of Part B is to determine the incidence rate of patients surviving and off mechanical ventilation at the end of day 28 with one of the key secondary endpoints being all-cause mortality. The Phase 2 clinical trial is anticipated to be completed in the second half of 2004.

The current standard of care for Acute Respiratory Distress Syndrome includes placing patients on mechanical ventilators in intensive care units at a cost per patient of approximately \$8,500 per day, typically for an average of 21 to 28 days. There are estimated to be between 150,000 and 200,000 adults per year in the United States suffering from Acute Respiratory Distress Syndrome with similar numbers afflicted in Europe. Because there are no approved treatments for these diseases, the mortality rate can range from 35% to 50%.

The FDA has granted us Fast-Track Status and Orphan Drug Designation for Surfaxin for the treatment of Acute Respiratory Distress Syndrome in adults. The European Medicines Evaluation Agency has granted us Orphan Product designation for Surfaxin for the treatment of Acute Lung Injury in adults (which in this circumstance is a larger patient population that encompasses Acute Respiratory Distress Syndrome). We were awarded and received a \$1 million Fast-Track Small Business Innovative Research Grant by the National Institutes of Health to develop Surfaxin for the treatment of Acute Respiratory Distress Syndrome and Acute Lung Injury in adults.

Aerosolized Surfactant (development name DSC 104) for Severe, Acute Asthma

Asthma is a common disease characterized by sudden constriction and inflammation of the lungs. Constriction of the upper airway system occurs when the airway muscles tighten, while inflammation is a swelling of the airways usually due to an allergic reaction caused by an airborne irritant. Both of these events cause airways to narrow and may result in wheezing, shortness of breath and chest tightness. Several studies have shown that surfactant damage and

dysfunction is a significant component of asthma -- airway constriction occurs when there is a surfactant dysfunction in the airways of the deep lung of the type that develops during an asthma attack. We believe that surfactant replacement therapy has the potential to relieve the constriction in the airways associated with asthma.

According to information provided by the American Lung Association, asthma afflicts more than 20,000,000 people in the United States and its incidence rate continues to rise. Asthma is a chronic disease; it is prevalent in people of all ages and an estimated 12,000,000 people have experienced an asthma attack within the past year. In the United States alone, there are roughly 1,000,000 hospital outpatient visits, approximately 1,800,000 emergency room visits and 9,300,000 physician visits each year due to asthma. Asthma ranks within the top 10 prevalent activity-limiting health conditions costing \$14 billion in United States healthcare costs annually.

Asthma may require life-long therapy to prevent or treat episodes. Ten percent of patients are considered severe asthmatics and require moderate to high doses of drugs. Currently available asthma medications include inhaled and oral steroids, bronchodilators and leukotriene antagonists. Bronchodilators cannot be used to control severe episodes or chronic, severe asthma. Oral steroids can cause serious side effects when used for prolonged periods and, thus, are typically limited to severe asthmatic episodes and chronic, severe asthma. We believe that supplying surfactant as an inhaled aerosol may relieve airway obstruction in the deep lung and lead to a more rapid improvement in asthmatic symptoms.

We recently completed a Phase 1b clinical trial to evaluate the safety and lung tolerability and deposition characteristics of our humanized lung surfactant, delivered as an inhaled aerosol to treat individuals who suffer from asthma. This masked, placebo-controlled, randomized, Phase 1b study included six healthy subjects and eight mild-persistent asthmatic patients. Results demonstrated that DSC-104 was safe and well tolerated, did not induce bronchospasm and was deposited to both the central and peripheral regions of the lungs in the mild-persistent asthmatic group and the healthy volunteers. We are presently preparing a follow-on Phase 2 dose escalation clinical trial evaluating the safety, tolerability and efficacy of DSC-104 to be conducted at several leading asthma clinics in the United States that we anticipate initiating in the second half of 2004.

Aerosolized Surfactant for Acute Lung Injury

Acute Lung Injury is associated with conditions that either directly or indirectly injure the air sacs of the lung. Acute Lung Injury is a syndrome of inflammation and increased permeability of the lungs with an associated breakdown of the lungs' surfactant layer. The most serious manifestation of Acute Lung Injury is Acute Respiratory Distress Syndrome.

Among the causes of Acute Lung Injury are complications typically associated with certain major surgeries, mechanical ventilator induced lung injury (often referred to as VILI), smoke inhalation, pneumonia and sepsis. There are an estimated 1 million patients at risk in the United States for Acute Lung Injury annually and there are no currently-approved therapies.

We are evaluating aerosolized formulations of our humanized surfactant to potentially treat Acute Lung Injury. We believe that our proprietary humanized aerosol surfactant may be effective as a preventive measure for patients at risk for Acute Lung Injury. This prophylactic approach may result in fewer patients requiring costly intensive care therapy, thereby eliminating long periods of therapy and offering cost savings in the hospital setting.

STRATEGIC ALLIANCES

Quintiles Transnational Corp., and PharmaBio Development Inc.

We have a collaboration arrangement with Quintiles Transnational Corp., and its affiliate, PharmaBio Development Inc., to provide certain commercialization services in the United States for Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants and Meconium Aspiration Syndrome in full-term infants. Quintiles is obligated to hire and train a dedicated United States sales force that will be branded in the market as ours. PharmaBio has agreed to fund up to \$70 million of the sales force costs as well as other sales and marketing costs for commercialization of Surfaxin in the United States for seven years. Additionally, the collaboration allows for this specialty sales force to become ours at the end of the seven year term, with an option to acquire it sooner.

Under the collaboration, we will receive 100% of the revenues from sales of Surfaxin and have agreed to pay PharmaBio a commission on net sales in the United States of Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants and Meconium Aspiration Syndrome in full-term infants and all "off-label" uses for 10 years following first launch of the product in the United States. The collaboration allows us to retain product ownership and to have sales and marketing expertise in place for the commercialization of Surfaxin, if approved.

PharmaBio also extended to us a secured revolving credit facility of up to \$8,500,000 to \$10,000,000 to fund pre-marketing activities associated with the launch of Surfaxin in the United States as we achieve certain milestones. We are obligated to use a significant portion of the funds borrowed under the credit facility for pre-launch marketing services to be provided by Quintiles. Principal amounts owed by us under the credit facility may be repaid out of the proceeds of milestone payments to be paid to us by PharmaBio upon the achievement of certain corporate milestones. See Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - Secured, Revolving Credit Facility and Capital Lease Arrangement."

Laboratorios del Dr. Esteve, S.A.

We have a strategic alliance with Laboratorios del Dr. Esteve to develop, market and sell Surfaxin throughout Europe and Latin America. Esteve will provide certain commercialization services for Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants and Acute Lung Injury/Acute Respiratory Distress Syndrome in adult patients. Our exclusive supply agreement with Esteve provides that Esteve will purchase from us all of its Surfaxin drug product requirements at an established transfer price based on sales of Surfaxin by Esteve and/or its sublicensee(s). Esteve has also agreed to sponsor certain clinical trial costs related to obtaining regulatory approval in Europe

for the Acute Lung Injury/Acute Respiratory Distress Syndrome indications. Esteve will make certain milestone payments to us upon the attainment of European marketing regulatory approval for Surfaxin. See Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - Secured, Revolving Credit Facility and Capital Lease Arrangement."

LICENSING ARRANGEMENTS; PATENTS AND PROPRIETARY RIGHTS

Patents and Proprietary Rights

Johnson & Johnson and The Scripps Research Institute

Our humanized surfactant platform technology, including Surfaxin, is based on the proprietary peptide, sinapultide, (a 21 amino acid protein-like substance that closely mimics the essential human lung protein SP-B). This technology was invented at The Scripps Research Institute and was exclusively licensed to, and further developed by, Johnson & Johnson and its wholly owned subsidiary, Ortho Pharmaceutical. We have received an exclusive, worldwide sublicense from Johnson & Johnson and Scripps for, and have rights to, a series of over 30 patents and patent filings (worldwide) which are important, either individually or collectively, to our strategy of commercializing our humanized surfactant technology for the diagnosis, prevention and treatment of disease. The sublicense gives us the rights to such patents for the life of the patents.

Patents covering our proprietary humanized surfactant technology that have been issued or are pending worldwide include composition of matter, formulation, manufacturing and uses, including the pulmonary lavage, or "lung wash" techniques. Our most significant patent rights principally consist of five issued United States patents: U.S. Patent No. 5,407,914; U.S. Patent No. 5,260,273; U.S. Patent No. 5,164,369; U.S. Patent No. 5,789,381; and U.S. Patent No. 6,013,619 (along with corresponding issued and pending foreign patents). These patents relate to engineered humanized pulmonary surfactants (including Surfaxin), certain related peptides (amino acid protein-like substances) and compositions, methods of treating respiratory distress syndromes with these surfactants and compositions, and our proprietary pulmonary lavage method of treating Respiratory Distress Syndrome with these surfactants. We also have certain pending United States and foreign patent applications that relate to methods of manufacturing certain peptides which may be used in the manufacture of Surfaxin and other aspects of our humanized surfactant technology.

In June 2003, we were issued United States Patent No. 6,613,734, which covers a wide variety of combinations of peptides, proteins and other molecules related to our proprietary humanized pulmonary surfactant technology. The patent also includes methods of making and using these molecules.

In October 2002, we were issued European Patent No. 59006, which covers claims directed to compositions that contain sinapultide and related peptides for use as a therapeutic surfactant for treating Respiratory Distress Syndrome and related conditions. We also have an issued European Patent, No. 0350506, covering certain other surfactant peptides.

U.S. Patent No. 6,013,619 was issued to Scripps and licensed to us, and covers all known engineered (including Surfaxin), animal- or human-derived surfactants for use in any form of pulmonary lavage for Respiratory Distress Syndromes. Our proprietary pulmonary lavage techniques (using surfactant) include lavage via a bronchoscope in adults as well as direct pulmonary lung lavage via an endotracheal tube in newborn babies with Meconium Aspiration Syndrome. Scientific rationale supports the premise that our proprietary lavage technique may provide a clinical benefit to the treatment of Acute Lung Injury/Acute Respiratory Distress Syndrome in adults and Meconium Aspiration Syndrome in full-term infants by decreasing the amount of infectious and inflammatory debris in the lungs, restoring the air sacs to a more normal state and possibly resulting in patients getting off mechanical ventilation sooner.

Such patents, which include relevant European patents, expire on various dates beginning in 2009 and ending 2017 or, in some cases, possibly later.

The Scripps Research Institute Research Agreement

We are parties with Scripps to a research funding and option agreement that expires in February 2005, subject to termination by us at any time with 90 days prior notice. Pursuant to this agreement, we fund a portion of Scripps' research efforts and are entitled to an option to acquire an exclusive worldwide license to the technology developed from the research program during the term of the agreement. Scripps owns all of the technology that it developed pursuant to work performed under the agreement. To the extent we do not exercise our option, we have the right to receive 50% of the net royalty income received by Scripps for inventions that we jointly develop under the agreement.

See Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operations - Risks Related to Our Business": " - If we cannot protect our intellectual property, other companies could use our technology in competitive products. If we infringe the intellectual property rights of others, other companies could prevent us from developing or marketing our products"; " - Even if we obtain patents to protect our products, those patents may not be sufficiently broad and others could compete with us"; " - Intellectual property rights of third parties could limit our ability to market our products"; and " - If we cannot meet requirements under our license agreements, we could lose the rights to our products."

MANUFACTURING AND DISTRIBUTION – THIRD PARTY SUPPLIERS

Manufacturing

Our humanized surfactant product candidates must be manufactured in a sterile environment and in compliance with current good manufacturing practice requirements (cGMPs) set by the FDA and other relevant worldwide regulatory authorities.

Our humanized surfactant product candidates are manufactured through the combination of sinapultide, which is provided by BACHEM California, Inc., and PolyPeptides Laboratories, Inc., and certain other active ingredients, including certain lipids, that are provided by other suppliers such as Genzyme Pharmaceuticals, a division of the Genzyme Corporation, and Avanti Polar Lipids.

Our humanized surfactant drug product, including Surfaxin, is manufactured using the ingredients discussed above with our own specialized equipment under the direction and supervision of our manufacturing and quality control personnel. Until recently, our drug product was manufactured at the sterile facilities of our primary contract manufacturer, Akorn, Inc., which was the only manufacturing facility that we had validated to produce clinical material of our humanized surfactant drug product, including Surfaxin. In October 2003, we transferred our manufacturing capabilities from Akorn to a new contract manufacturer, Laureate Pharma, L.P., to install and validate a manufacturing and filling line at their facility for the production of clinical and commercial drug supply in conformance with cGMPs. All steps required for production of cGMP material have been completed and we are presently producing Surfaxin for our Phase 2 trial for the treatment of Acute Respiratory Distress Syndrome.

We now anticipate that our manufacturing capabilities through Laureate should allow sufficient commercial production of Surfaxin, if approved, to supply the present worldwide demand for the treatment of Respiratory Distress Syndrome in premature infants and Meconium Aspiration Syndrome in full-term infants. We expect these capabilities to allow us to provide adequate supply of Surfaxin for our planned clinical trials for the treatment of Acute Respiratory Distress Syndrome in adults.

To support a long-term manufacturing strategy for the production of clinical and commercial supply of our humanized surfactant drug product, we are evaluating further development and scale-up of our current contract manufacturer, alternative contract manufacturers and building our own manufacturing operations in order to secure additional manufacturing capabilities to meet our production needs as they expand. We will rely on outside manufacturers for production of our products after marketing approval.

Should the proper financial and other resources be available, our manufacturing process for our humanized surfactant drug product allows us to scale-up production of our humanized surfactant drug product, including Surfaxin. The scaling up of the currently-approved, animal-derived products is significantly less efficient, if at all possible. By scaling up our production, we should be able to produce sufficient drug products to potentially treat diseases with larger patient populations, such as Acute Respiratory Disease Syndrome in adults, Respiratory Dysfunction in premature infants, asthma, Acute Lung Injury, COPD and other broader respiratory diseases and upper airway disorders.

Manufacturing or quality control problems could occur at Laureate or our other contract manufacturers, causing production and shipment delays or a situation where the contractor may not be able to maintain compliance with the FDA's GMP requirements necessary to continue manufacturing our ingredients or drug product. If any such suppliers or manufacturers of our products fail to comply with cGMP requirements or other FDA and comparable foreign regulatory requirements, it could adversely affect our clinical research activities and our ability to market and develop our products. See Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operations - Risks Related to Our Business": " - If the parties we depend on for manufacturing our pharmaceutical products do not timely supply these products, it may delay or impair our ability to develop and market our products"; and " - In order

to conduct our clinical trials we need adequate supplies of our drug substance and drug product and competitor's drug product, which may not be readily available."

Distribution

Our collaboration agreement with Quintiles to provide certain commercialization services in the United States for Surfaxin does not encompass distribution services. We are currently evaluating third party distribution capability in order to commercialize Surfaxin in the United States.

Our collaboration with Esteve provides that Esteve has the responsibility for distribution throughout Europe and Latin America. See Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operations - Risks Related to Our Business - Our lack of marketing and sales experience could limit our ability to generate revenues from future product sales."

COMPETITION

We are engaged in highly competitive fields of pharmaceutical research. Competition from numerous existing companies and others entering the fields in which we operate is intense and expected to increase. We expect to compete with, among others, conventional pharmaceutical companies. Most of these companies have substantially greater research and development, manufacturing, marketing, financial, technological personnel and managerial resources than we do. Acquisitions of competing companies by large pharmaceutical or health care companies could further enhance such competitors' financial, marketing and other resources. Moreover, competitors that are able to complete clinical trials, obtain required regulatory approvals and commence commercial sales of their products before we do may enjoy a significant competitive advantage over us. There are also existing therapies that may compete with the products we are developing. See Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operations - Risks Related to Our Business - Our industry is highly competitive and we have less capital and resources than many of our competitors, which may give them an advantage in developing and marketing products similar to ours or make our products obsolete."

Presently, the FDA has approved surfactants as replacement therapy only for the treatment of Respiratory Distress Syndrome in premature infants, a condition in which infants are born with an insufficient amount of their own natural surfactant. The most commonly used of these approved replacement surfactants are derived from a chemical extraction process of pig and cow lungs. Curosurf[®] is a porcine lung extract that is marketed in Europe by Chiesi Farmaceutici S.p.A., and in the United States by Dey Laboratories, Inc. Survanta[®], marketed by the Ross division of Abbott Laboratories, Inc., is derived from minced cow lung that contains the cow version of surfactant protein B. Forest Laboratories, Inc., markets its calf lung surfactant extract, Infasurf[®], in the United States.

There is presently only one approved synthetic surfactant available, Exosurf[®], marketed by GlaxoSmithKline, plc. However, this product does not contain any surfactant proteins, is not widely used and its active marketing recently has been discontinued by its manufacturer.

With respect to the development of lung surfactants for the treatment of other respiratory diseases and upper airway disorders, with the exception of one porcine-derived surfactant drug candidate under development by Leo Pharma A/S in Denmark, we are not aware of any other lung surfactant currently under development.

There are no drugs currently approved that are specifically indicated for the treatment of Acute Respiratory Distress Syndrome in adults or Meconium Aspiration Syndrome in full-term infants. Current therapy consists of general supportive care and mechanical ventilation. There are a significant number of other potential therapies in development for the treatment of Acute Respiratory Distress Syndrome in adults that are not surfactant related. Any of these various drugs or devices could significantly impact the commercial opportunity for Surfaxin.

Our humanized surfactant product candidates, including Surfaxin, are engineered versions of natural human lung surfactant and contain our humanized peptide, sinapultide. We believe that our engineered humanized surfactant can be manufactured less expensively than the animal-derived surfactants, in sufficient quantities, in exact and consistent pharmaceutical grade quality, and has no potential to cause adverse immunological responses in young and older adults, all important attributes to potentially meet significant unmet medical needs. Our products also have the ability to be more precisely formulated, such as in the form of aerosolized liquids or dry powders to address various medical indications. In addition, we believe that our engineered humanized surfactant might possess other pharmaceutical benefits not currently found with the animal surfactants such as longer shelf-life, reduced number of administrations to the patient's lungs and elimination of the risk of animal-borne diseases including the brain-wasting bovine spongiform encephalopathy (commonly called "mad-cow disease").

GOVERNMENT REGULATION

The testing, manufacture, distribution, advertising and marketing of drug products are subject to extensive regulation by federal, state and local governmental authorities in the United States, including the FDA, and by similar agencies in other countries. Any product that we develop must receive all relevant regulatory approvals or clearances before it may be marketed in a particular country.

The regulatory process, which includes preclinical studies and clinical trials of each pharmaceutical compound to establish its safety and efficacy and confirmation by the FDA that good laboratory, clinical and manufacturing practices were maintained during testing and manufacturing, can take many years, requires the expenditure of substantial resources and gives larger companies with greater financial resources a competitive advantage over us. Delays or terminations of clinical trials we undertake would likely impair our development of product candidates. Delays or terminations could result from a number of factors, including stringent enrollment criteria, slow rate of enrollment, size of patient population, having to compete with other clinical trials for eligible patients, geographical considerations and others.

The FDA review process can be lengthy and unpredictable, and we may encounter delays or rejections of our applications when submitted. If questions arise during the FDA review process, approval may take a significantly longer period of time. Generally, in order to gain FDA

approval, we first must conduct preclinical studies in a laboratory and in animal models to obtain preliminary information on a compound's efficacy and to identify any safety problems. The results of these studies are submitted as part of an IND (Investigational New Drug) application that the FDA must review before human clinical trials of an investigational drug can start.

Clinical trials are normally done in three sequential phases and generally take two to five years or longer to complete. Phase 1 consists of testing the drug product in a small number of humans, normally healthy volunteers, to determine preliminary safety and tolerable dose range. Phase 2 usually involves studies in a limited patient population to evaluate the effectiveness of the drug product in humans having the disease or medical condition for which the product is indicated, determine dosage tolerance and optimal dosage and identify possible common adverse effects and safety risks. Phase 3 consists of additional controlled testing at multiple clinical sites to establish clinical safety and effectiveness in an expanded patient population of geographically dispersed test sites to evaluate the overall benefit-risk relationship for administering the product and to provide an adequate basis for product labeling. Phase 4 clinical trials may be conducted after approval to gain additional experience from the treatment of patients in the intended therapeutic indication.

After completion of clinical trials of a new drug product, FDA and foreign regulatory authority marketing approval must be obtained. A New Drug Application submitted to the FDA generally takes one to three years to obtain approval. If questions arise during the FDA review process, approval may take a significantly longer period of time. The testing and approval processes require substantial time and effort and we may not receive approval on a timely basis, if at all. Even if regulatory clearances are obtained, a marketed product is subject to continual review, and later discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. For marketing outside the United States, we also will be subject to foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. None of our products under development have been approved for marketing in the United States or elsewhere. We may not be able to obtain regulatory approval for any such products under development. Failure to obtain requisite governmental approvals or failure to obtain approvals of the scope requested will delay or preclude us, or our licensees or marketing partners, from marketing our products, or limit the commercial use of our products, and thereby would have a material adverse effect on our business, financial condition and results of operations. See Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operations - Risks Related to Our Business": " - Our technology platform is based solely on our proprietary humanized, engineered surfactant technology. Our ongoing clinical trials for our lead surfactant replacement technologies may be delayed, or fail, which will harm our business"; and " - The clinical trial and regulatory approval process for our products is expensive and time consuming, and the outcome is uncertain."

The FDA has granted us Fast-Track Approval Designation for the indications of Acute Respiratory Distress Syndrome and Meconium Aspiration Syndrome. Fast-Track Status facilitates the development and expedites the review of new drugs intended for treatment of life-

threatening conditions for which there are presently no medical options or an unmet medical need by providing for the FDA's review of the New Drug Application within six months following filing. We have also received Orphan Drug Designation from the FDA's Office of Orphan Products Development for Surfaxin as a treatment for Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants, and Acute Respiratory Distress Syndrome in adults. Surfaxin has received designation as an Orphan Product for Meconium Aspiration Syndrome and Acute Lung Injury (which, in this circumstance, encompasses Acute Respiratory Distress Syndrome) from the European Medicines Evaluation Agency (EMA).

EMPLOYEES

We have approximately 75 full-time employees, primarily employed in the United States, Europe and Latin America. Our future success depends in significant part upon the continued service of our key scientific personnel and executive officers and our continuing ability to attract and retain highly qualified scientific and managerial personnel. There is a competitive market for such personnel and we may not be able to retain our key employees or attract, assimilate or retain other highly qualified technical and managerial personnel in the future. See Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operations - Risks Related to Our Business - We depend upon key employees and consultants in a competitive market for skilled personnel. If we are unable to attract and retain key personnel, it could adversely affect our ability to develop and market our products."

AVAILABLE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy any document we file with the Commission at the Commission's public reference rooms at 450 Fifth Street, N.W., Washington, D.C. 20549, 233 Broadway, New York, New York 10279, and Citicorp Center, 500 West Madison Street, Suite 1400, Chicago, Illinois 60661- 2511. Please call the Commission at 1-800-SEC-0330 for further information on the public reference rooms. Our Commission filings are also available to the public from the Commission's Website at "<http://www.sec.gov>." We make available free of charge our annual, quarterly and current reports, proxy statements and other information upon request. To request such materials, please send an e-mail to ir@DiscoveryLabs.com or contact John G. Cooper, our Executive Vice President, Chief Financial Officer at our address as set forth above.

We maintain a Website at "<http://www.DiscoveryLabs.com>" (this is not a hyperlink, you must visit this website through an Internet browser). Our Website and the information contained therein or connected thereto are not incorporated into this Annual Report on Form 10-K.

ITEM 2. PROPERTIES.

Our principal offices and quality control laboratory facility is located at 350 South Main Street, Suite 307, Doylestown, Pennsylvania 18901. The telephone number of our executive office is

(215) 340-4699 and the facsimile number is (215) 340-3940. In January 2002, we established a research facility in Redwood City, California, to develop aerosolized formulations of our proprietary humanized surfactant. We lease all of these properties. In December 2003, we closed our satellite office in the United Kingdom.

ITEM 3. LEGAL PROCEEDINGS.

We are not aware of any pending or threatened legal actions other than disputes arising in the ordinary course of our business that would not, if determined adversely to us, have a material adverse effect on our business and operations.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

No matters were submitted to a vote of security holders during the fourth quarter of 2003.

PART II

ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

Our common stock is traded on the Nasdaq SmallCap Market under the symbol "DSCO." As of February 29, 2004, the number of stockholders of record of shares of our common stock was approximately 186, and the number of beneficial owners of shares of our common stock was approximately 12,000. As of February 29, 2004, there were approximately 43,697,370 shares of our common stock issued and outstanding.

The following table sets forth the quarterly price ranges of our common stock for the periods indicated, as reported by Nasdaq.

First Quarter 2002	\$2.70	\$4.19
Second Quarter 2002.....	\$1.28	\$3.26
Third Quarter 2002	\$0.90	\$1.97
Fourth Quarter 2002.....	\$1.60	\$3.20
First Quarter 2003	\$1.32	\$2.94
Second Quarter 2003.....	\$1.56	\$7.40
Third Quarter 2003	\$6.12	\$8.50
Fourth Quarter 2003	\$5.40	\$10.75
First Quarter 2004 (through February 29, 2004)	\$10.00	\$13.32

We have not paid dividends on our common stock. It is anticipated that we will not pay dividends on our common stock in the foreseeable future.

Sales of Unregistered Securities

During the year ended December 31, 2003, we granted an aggregate of 1,112,000 options to our officers, directors, employees and consultants at various exercise prices ranging from \$1.70 per share to \$9.17 per share. These securities were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) of the Securities Act of 1933 as transactions not involving any public offering. No broker/dealers were involved in the sale and no commissions were paid. The recipients of these options either received adequate information about us or had access, through employment or other relationships, to such information.

ITEM 6. SELECTED FINANCIAL DATA

Consolidated Statement of Operations Data: (in thousands, except per share data)

	For the year ended December 31,				
	2003	2002	2001	2000	1999
Revenues from collaborative agreements	\$ 1,037	\$ 1,782	\$ 1,112	\$ 741	\$ 178
Operating Expenses:					
Research and development	19,750	14,347	8,007	7,494	2,869
General and administrative	5,722	5,458	5,067	5,145	2,421
Total expenses	25,472	19,805	13,074	12,639	5,290
Operating loss	(24,435)	(18,023)	(11,962)	(11,898)	(5,112)
Other income and expense	155	580	816	1,037	154
Net loss	\$ (24,280)	\$ (17,443)	\$ (11,146)	\$ (10,861)	\$ (4,958)
Net loss per common share - basic and diluted	\$ (0.65)	\$ (0.64)	\$ (0.51)	\$ (0.58)	\$ (0.66)
Weighted average number of common shares outstanding	37,426	27,351	22,038	18,806	7,545

Consolidated Balance Sheet Data: (in thousands)

	For the year ended December 31,				
	2003	2002	2001	2000	1999
ASSETS					
Current Assets:					
Cash/cash equivalents and marketable securities	\$ 29,422	\$ 19,152	\$ 16,696	\$ 18,868	\$ 3,547
Prepaid expenses and other current assets	668	327	1,582	149	641
Total current assets	30,090	19,479	18,278	19,017	4,188
Property and equipment, net of depreciation	2,414	1,231	822	697	426
Other assets	211	352	965	3	18
Total assets	\$ 32,715	\$ 21,062	\$ 20,065	\$ 19,717	\$ 4,632
LIABILITIES AND STOCKHOLDERS' EQUITY					
Credit facility with corporate partner - current	\$ 2,436	\$ -	\$ -	\$ -	\$ -
Other current liabilities	4,593	3,202	1,794	2,399	440
Total current liabilities	7,029	3,202	1,794	2,399	440
Deferred revenue	672	1,393	615	851	1,036
Credit facility with corporate partner	-	1,450	-	-	-
Capitalized lease	711	256	33	31	48
Total liabilities	8,412	6,301	2,442	3,281	1,524
Stockholders' equity	24,303	14,761	17,623	16,436	3,108
Total liabilities and stockholders' equity	\$ 32,715	\$ 21,062	\$ 20,065	\$ 19,717	\$ 4,632
Common Stock, \$0.001 par value, issued	42,491	32,818	25,546	20,871	9,689

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operations" should be read in connection with our Consolidated Financial Statements. See Item 15: "Exhibits, Financial Statement Schedules, and Reports on Form 8-K."

Overview

We are a biopharmaceutical company developing our proprietary humanized lung surfactant technology as Surfactant Replacement Therapies for respiratory diseases. Surfactants are compositions produced naturally in the lungs and are essential to the lungs' ability to absorb oxygen and to maintain proper airflow through the respiratory system. The absence or depletion of surfactants is involved in a number of respiratory diseases.

Our technology produces an engineered version of natural human lung surfactant that is designed to closely mimic the essential properties of human lung surfactant. We believe that our surfactant technology provides the opportunity, for the first time, for pulmonary surfactants to be developed into a series of respiratory therapies for critical care and other hospitalized patients where there are few or no approved therapies available.

We recently completed two Phase 3 clinical trials of Surfaxin, our lead product, for the treatment of Respiratory Distress Syndrome in premature infants and are preparing to file new drug applications with the FDA and other regulatory authorities in the rest of the world.

Our Surfactant Replacement Therapy is also in a Phase 2 clinical trial for the treatment of Acute Respiratory Distress Syndrome in adults, as well as a Phase 3 and Phase 2 clinical trial for the treatment of Meconium Aspiration Syndrome in full-term infants. In addition, we recently completed a successful Phase 1b clinical trial in healthy volunteers and mild asthmatics and are currently preparing to initiate a follow-on Phase 2 clinical trial evaluating the safety, tolerability and efficacy of our humanized lung surfactant, delivered as an inhaled aerosol (development name DSC-104), to treat patients with asthma.

Presently, we are evaluating the development of other aerosolized formulations of our humanized surfactant to potentially treat premature infants in Neonatal Intensive Care Units suffering from Respiratory Dysfunction. We are also evaluating aerosolized formulations of our humanized surfactant to potentially treat Acute Lung Injury, chronic obstructive pulmonary disease (often referred to as COPD, which is a chronic condition of the lung that prevents enough oxygen from reaching the blood), rhinitis, sinusitis (infection of the sinuses), sleep apnea and otitis media (inner ear infection).

We are presently implementing a long-term commercial strategy which includes manufacturing for the production of our humanized surfactant drug products to meet anticipated clinical and commercial needs and sales and marketing capabilities to execute the launch of Surfaxin in the U.S. and Europe, if approved.

Since our inception, we have incurred significant losses and, as of December 31, 2003, we had an accumulated deficit of approximately \$97,000,000 (including historical results of predecessor companies). The majority of our expenditures to date have been for research and development activities. Research and development expenses represent costs incurred for scientific and clinical personnel, clinical trials, regulatory filings and manufacturing efforts (including raw material costs). We expense our research and development costs as they are incurred. General and administrative expenses consist primarily of executive management, financial, business development, legal and general corporate activities and related expenses. See Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operations - Plan of Operations."

Historically, we have funded our operations with working capital provided principally through public and private equity financings and strategic collaborations. As of December 31, 2003, we had cash and investments of approximately \$29,400,000, a secured revolving credit facility of \$8,500,000 to \$10,000,000 with PharmaBio, of which \$5,700,000 was available for borrowing and \$2,400,000 was outstanding, and a \$4,000,000 capital equipment lease financing arrangement of which approximately \$962,000 was outstanding. See Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources."

Critical Accounting Policies

The preparation of financial statements, in conformity with accounting principles generally accepted in the United States, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

We have identified below some of our more critical accounting policies and changes to accounting policies. For further discussion of our accounting policies see Note 2 "Summary of Significant Accounting Policies" in the Notes to Consolidated Financial Statements. See Item 15: "Exhibits, Financial Statement Schedules, and Reports on Form 8-K."

Revenue Recognition- research and development collaborative agreements

For up-front payments and licensing fees related to our contract research or technology, we defer and recognize revenue as earned over the life of the related agreement. Milestone payments are recognized as revenue upon achievement of contract-specified events and when there are no remaining performance obligations.

Revenue earned under our research and development collaborative agreement contracts is recognized over a number of years as we perform research and development activities. For up-front payments and licensing fees related to our contract research or technology, we defer and recognize revenue as earned over the estimated period in which the services are expected to be performed.

Research and Development Costs

Research and development costs are expensed as incurred. We will continue to incur research and development costs as we continue to expand our product development activities. Our research and development costs have included, and will continue to include, expenses for internal development personnel, supplies and facilities, clinical trials, regulatory compliance and reviews, validation of processes and start up costs to establish commercial manufacturing capabilities. By the time our product candidates are approved by the FDA and we begin commercial manufacturing, we will no longer expense certain manufacturing costs as research and development costs.

Plan of Operations

We expect to continue to incur increasing operating losses for the foreseeable future, primarily due to our continued research and development activities attributable to new and existing products, manufacturing, commercialization, and general and administrative activities.

We anticipate that during the next 12 to 24 months we will:

- (i) increase our research, development and regulatory activities in an effort to develop a broad pipeline of potential Surfactant Replacement Therapies for respiratory diseases.

We recently completed two Phase 3 clinical trials of Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants and we are now preparing to file new drug applications with the FDA and other regulatory authorities in the rest of the world. Filing of the NDA is anticipated in April 2004. In accordance with the trial design for both Phase 3 studies, we continue to conduct six and twelve month clinical follow-up on all enrolled patients. For Acute Respiratory Distress Syndrome in adults, we currently are conducting a Phase 2 dose-ranging safety and efficacy study of up to 110 patients in the United States. We expect to have the results from this trial in the second half of 2004. For Meconium Aspiration Syndrome in full-term infants, we currently are conducting a Phase 3 clinical trial in up to 200 patients and a Phase 2 clinical trial in up to 60 patients. Both trials are expected to be completed in 2005. We recently completed a successful Phase 1b clinical trial intended to evaluate the tolerability and lung deposition of our humanized lung surfactant, delivered as an inhaled aerosol (development name DSC-104), to treat patients with asthma and are currently preparing to initiate a follow-on Phase 2 clinical trial. We are evaluating the development of aerosolized formulations of our humanized surfactant to potentially treat premature infants in Neonatal Intensive Care Units suffering from Respiratory Dysfunction and are preparing to initiate a clinical trial in the second half of 2004. In addition, we are evaluating the development of aerosolized formulations of our humanized surfactant to potentially treat Acute Lung Injury, COPD, rhinitis, sinusitis, sleep apnea and otitis media (inner ear infection).

The drug development, clinical trial and regulatory process is lengthy, expensive and uncertain and subject to numerous risks including, without limitation, the following risks discussed in the "Risks Related to Our Business" - "Our technology platform is based

solely on our proprietary humanized, engineered surfactant technology. Our ongoing clinical trials for our lead surfactant replacement therapies may be delayed, or fail, which will harm our business"; - "The clinical trial and regulatory approval process for our products is expensive and time consuming, and the outcome is uncertain."

- (ii) invest in and support a long-term manufacturing strategy for the production of our humanized surfactant drug product including further development and scale-up of our current contract manufacturer, alternative contract manufacturers and building our own manufacturing operations in order to secure additional manufacturing capabilities to meet production needs as they expand.
- (iii) invest in marketing and commercialization (including distribution) resources to execute the launch of Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants, if approved, and the execution of our "Discovery/Surfaxin" worldwide sales and marketing strategy.
- (iv) invest in additional general and administrative resources primarily to support our business development initiatives, financial systems and controls and management information technologies.

We are currently implementing the initial phase of our long-term manufacturing strategy through the recent selection of Laureate to become our current contract manufacturer. In October 2003, we entered into a Technology Transfer and Manufacturing Agreement with Laureate which provides for the establishment of a Surfaxin manufacturing line together with the production of clinical and commercial drug supply in conformance with current Good Manufacturing Practices (cGMP). This agreement also encompasses plans for manufacturing scale-up and enhancements, including additional equipment to support our anticipated commercial-scale requirements of Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants and our anticipated clinical-scale production requirements of Surfaxin for the treatment of Acute Respiratory Distress Syndrome in adults. See "Risks Related to Our Business - In order to conduct our clinical trials we need adequate supplies of our drug substance and drug product and competitor's drug product, which may not be readily available"; and "If the parties we depend on for manufacturing our pharmaceutical products do not timely supply these products, it may delay or impair our ability to develop and market our products."

We have a collaboration arrangement with Quintiles, and its affiliate, PharmaBio, to provide certain commercialization services in the United States for Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants and Meconium Aspiration Syndrome in full-term infants. Quintiles is obligated to hire and train a dedicated United States sales force that will be branded in the market as ours. Quintiles has committed to make available up to \$70,000,000 in post-launch funding to cover the first seven years of United States sales and marketing costs. In return, Quintiles is entitled to receive a commission on net sales of Surfaxin over a 10-year period. The Quintiles arrangement allows us to retain product ownership and have sales and marketing expertise in place for the commercialization of Surfaxin in the United States, if approved.

We have a strategic alliance with Esteve to develop, market and sell Surfaxin throughout Europe and Latin America. Esteve will provide certain commercialization services for Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants and Acute Lung Injury/Acute Respiratory Distress Syndrome in adult patients. Our exclusive supply agreement with Esteve provides that Esteve will purchase from us all of its Surfaxin drug product requirements at an established transfer price based on sales of Surfaxin by Esteve and/or its sublicensee(s). Esteve has also agreed to sponsor certain clinical trial costs related to obtaining regulatory approval in Europe for the indications of Acute Lung Injury/Acute Respiratory Distress Syndrome. Esteve also agreed to make certain milestone payments to us upon the attainment of European marketing regulatory approval for Surfaxin.

We will need to generate significant revenues from product sales and or related royalties and transfer prices to achieve and maintain profitability. Through December 31, 2003, we had no revenues from any product sales, and have not achieved profitability on a quarterly or annual basis. Our ability to achieve profitability depends upon, among other things, our ability to develop products, obtain regulatory approval for products under development and enter into agreements for product development, manufacturing and commercialization. In addition, our results are dependent upon the performance of our strategic partners and third party contract manufacturers and suppliers. Moreover, we may never achieve significant revenues or profitable operations from the sale of any of our products or technologies.

Through December 31, 2003, we had not generated taxable income. On December 31, 2003, net operating losses available to offset future taxable income for Federal tax purposes were approximately \$91,585,000. The future utilization of such loss carryforwards may be limited pursuant to regulations promulgated under Section 382 of the Internal Revenue Code. In addition, we have a research and development tax credit carryforward of \$1,868,000. The Federal net operating loss and research and development tax credit carryforwards expire beginning in 2008 and continuing through 2021.

Results of Operations

The net loss for the three years ended December 31, 2003, 2002 and 2001 was \$24,280,000 (or \$0.65 per common share), \$17,443,000 (or \$0.64 per common share) and \$11,146,000 (or \$0.51 per common share), respectively. These increased losses were primarily the result of increasing research and development expenditures as discussed below.

Revenue

Total revenues recognized for the three years ended December 31, 2003, 2002 and 2001 were \$1,037,000, \$1,782,000 and \$1,112,000, respectively. These revenues are associated with our research and development collaborative arrangements, primarily our alliance with Esteve to develop, market and sell Surfaxin throughout Europe and Latin America. Additional collaborative revenues relate to our Small Business Innovative Research (SBIR) grant to develop Surfaxin for Acute Lung Injury/Acute Respiratory Distress Syndrome in adults and our Orphan Products Development grant to develop Surfaxin for Meconium Aspiration Syndrome in full-term infants. The decrease in 2003 reflects: (i) the conclusion of our Small Business Innovative

Research (SBIR) grant for research for treatments of Acute Lung Injury/Acute Respiratory Distress Syndrome in adults and our Orphan Products Development grant to develop Surfaxin for Meconium Aspiration Syndrome in full-term infants; and (ii) the extension of the amortization period and related revenue recognition of the funding previously provided to us in connection with our strategic alliance with Esteve.

Expenses

Research and development expenses for the three years ended December 31, 2003, 2002 and 2001 were \$19,750,000, \$14,347,000 and \$8,007,000, respectively. The increases primarily reflect costs incurred for the: (i) development and regulatory efforts to complete the two Phase 3 clinical trials for Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants; (ii) Phase 2 clinical trial for Surfaxin for the treatment of Acute Respiratory Distress Syndrome in adults; (iii) investment in our clinical, statistical and regulatory infrastructure to manage the various development activities associated with our surfactant replacement therapy pipeline; (iv) research and development activities related to the development of aerosolized formulations of our humanized lung surfactant; and (v) activities associated with the installation and validation of our Surfaxin manufacturing and filling line at Laureate's facility for the production of clinical and commercial drug supply in conformance with current Good Manufacturing Practices (cGMPs).

General and administrative expenses for the three years ended December 31, 2003, 2002 and 2001 were \$5,722,000, \$5,458,000 and \$5,067,000, respectively. General and administrative expenses consist primarily of the costs of executive management, financial and accounting, business and commercial development, legal, facility and other administrative costs. Included in general and administrative costs are approximately \$986,000 and \$1,450,000 for the years ended December 31, 2003 and 2002, respectively, related to pre-launch commercialization activities for Surfaxin conducted in connection with a collaboration agreement with Quintiles (for which funding is provided by the secured, revolving credit facility with PharmaBio, discussed below in "Liquidity and Capital Resources"). Additionally, included in general and administrative costs for the years ended December 31, 2003, 2002 and 2001, are non-cash compensation charges of \$207,000, \$403,000 and \$517,000, respectively. The 2003 non-cash compensation charge is primarily related to the grant of stock options to non-employee members of our Board of Directors under our Amended and Restated 1998 Stock Option Plan and the vesting of certain stock options granted to consultants. The 2002 and 2001 non-cash compensation charges primarily relate to the grant of stock options to non-employee members of our Board of Directors under our stock option plan and certain modifications to certain options held by three departing members of our Board of Directors.

Other Income and Expense

Other income and expense (net) for the years ended December 31, 2003, 2002 and 2001 were \$155,000, \$580,000 and \$816,000, respectively. Interest income for the years ended December 31, 2003, 2002 and 2001 was \$452,000, \$724,000 and \$842,000, respectively, the decreases are primarily due to a reduction in interest earned on our cash, cash equivalents and marketable securities primarily due to a general reduction in earned market interest rates. Interest expense

for the years ended December 31, 2003, 2002 and 2001 was \$297,000, \$144,000 and \$26,000, respectively, the increases are due to interest expense associated with our secured, revolving credit facility and capital lease financing arrangements. See "Liquidity and Capital Resources."

Liquidity and Capital Resources

Cash, Cash Equivalents and Marketable Securities

As of December 31, 2003, we had cash, cash equivalents and marketable securities of approximately \$29,400,000 as compared to approximately \$19,200,000 as of December 31, 2002. As of December 31, 2003, we had working capital of approximately \$23,100,000 as compared to the working capital of approximately \$16,300,000 as of December 31, 2002. The increase in working capital is due to the net proceeds of \$34,800,000 received primarily from the sale of securities and the exercise of certain options and warrants, offset by funds used for operating activities and the classification to current liabilities of the \$2,400,000 outstanding as of December 31, 2003, under the secured, revolving credit facility with PharmaBio, discussed below.

Secured, Revolving Credit Facility and Capital Lease Arrangement

We have a secured revolving credit facility of up to \$8,500,000 to \$10,000,000 with PharmaBio to fund pre-marketing activities for a Surfaxin launch in the United States. The credit facility is available for use until December 10, 2004, and monies become available in three tranches upon satisfying certain conditions. We have satisfied the conditions for availability of the first two tranches and at December 31, 2003, the amount available under the credit facility was approximately \$5,700,000, of which \$2,400,000 was outstanding. Interest on amounts advanced under the credit facility are payable quarterly in arrears. Outstanding principal and interest due under the credit facility are due and payable on December 10, 2004. Although we may repay principal amounts owed by us under the credit facility from proceeds of milestone payments to be paid to us by PharmaBio upon the achievement of certain corporate milestones, there can be no assurance that we will achieve any of these milestones prior to the repayment date, and doing so is not likely unless the FDA expedites the review of the NDA for Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants that we expect to file with the FDA in April 2004, and approves such NDA prior to December 10, 2004. See Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operations - Risks Related to our Business - The clinical trial and regulatory approval process for our products is expensive and time consuming, and the outcome is uncertain." We are obligated to use a significant portion of the funds borrowed under the credit facility for pre-launch marketing services to be provided by Quintiles.

We have a capital lease financing arrangement with the Life Science and Technology Finance Division of General Electric Capital Corporation. In September 2003, the arrangement was increased to provide, subject to certain conditions, up to an aggregate \$4,000,000 in financing for capital purchases. As of December 31, 2003, approximately \$962,000 was outstanding under this financing arrangement.

We believe our current working capital is sufficient to meet our planned research and development and operational activities into 2005. We will need additional financing from investors or collaborators to complete research and development and commercialization of our current product candidates under development.

Our working capital requirements will depend upon numerous factors, including, without limitation, the progress of our research and development programs, clinical trials, timing and cost of obtaining regulatory approvals, timing and cost of pre-launch marketing activities, levels of resources that we devote to the development of manufacturing and marketing capabilities, levels of resources that our collaboration partners devote to the development of sales and marketing capabilities, technological advances, status of competitors and our ability to establish collaborative arrangements with other organizations, the ability to defend and enforce our intellectual property rights and the establishment of additional strategic or licensing arrangements with other companies or acquisitions.

Historically, the Company's working capital has been provided from the proceeds of private financings and strategic alliances:

In June and July of 2003, our common stock attained certain price performance thresholds on the Nasdaq SmallCap Market that permitted us to provide notice for redemption (and thereby effectively compel the exercise thereof) to the holders of three of our outstanding classes of warrants which represented, in aggregate, the right to purchase approximately 3.6 million shares of common stock. Such warrants (i.e., the Class I, Class F and Class C warrants) were previously issued by us in connection with certain private placement financings that occurred in November 2002, October 2001, and April 1999, respectively. Between the dates of June 1, 2003, and September 12, 2003, holders of warrants exercisable for approximately 3.6 million shares of common stock exercised such warrants, in accordance with their respective terms, either cashlessly or for cash, resulting in the issuance to the holders of approximately 3.3 million shares of common stock and our receipt of aggregate cash proceeds equal to approximately \$6,100,000.

In June 2003, we completed the sale of securities in a private placement to selected institutional and accredited investors for net proceeds of approximately \$26,100,000. We issued 4,997,882 shares of common stock and 999,577 Class A Investor warrants to purchase shares of common stock at an exercise price equal to \$6.875 per share. The Class A Investor warrants have a seven-year term.

In November 2002, we completed the sale of securities in a private placement to selected institutional and accredited investors for net proceeds of approximately \$11,900,000. We issued 6,397,517 shares of common stock and 2,878,883 Class I Warrants to purchase shares of Common Stock at an exercise price of \$2.425 per share. The Class I warrants had a five-year term and we were entitled to redeem the Class I warrants, with 60 days' prior written notice, for \$.001, upon the attainment of certain exchange-related price performance thresholds of the common stock. In June 2003, the price performance criteria was met and we provided notice to the Class I warrant holders of our intention to redeem the Class I warrants. All Class I warrants have been exercised.

Pursuant to our collaboration arrangement with Esteve on March 6, 2002, we issued 821,862 shares of common stock to Esteve at a purchase price equal to \$4.867 per share and received a licensing fee of \$500,000, for approximate net aggregate proceeds of \$4,450,000. See Item 1: "Business – Strategic Alliances."

Pursuant to the collaboration arrangement we entered into with Quintiles and PharmaBio in December 2001, we issued to PharmaBio, for approximate net aggregate proceeds of \$2,700,000: (i) 791,905 shares of common stock at a price equal to \$3.79 per share; and (ii) Class G warrants to purchase 357,143 shares of common stock at an exercise price equal to \$3.485 per share (subject to adjustment). In connection with the credit facility, we issued to PharmaBio Class H warrants to purchase 320,000 shares of common stock. The Class H warrants are exercisable at \$3.03 per share (subject to adjustment) and are exercisable proportionately only upon availability of the credit facility. To the extent the credit facility availability is increased to greater than \$8,500,000, for each \$1,000,000 increase, the amount of shares of common stock issuable pursuant to the Class H warrants shall be increased by approximately 38,000 shares. See Item 1: "Business – Strategic Alliances."

In October 2001, we received approximately \$7,300,000 in net proceeds from a private financing. In the financing, we issued 3,562,759 shares of common stock and 712,553 Class F warrants to purchase shares of common stock at an exercise price of \$2.365 per share. The Class F warrants had a five-year term and we were entitled to redeem the Class F warrants, with 20 days' prior written notice, for \$.001, upon the attainment of certain exchange-related price performance thresholds of the common stock. In July 2003, the price performance criteria was met and we provided notice to the Class F warrant holders of our intention to redeem the Class F warrants. All Class F warrants have been exercised.

In April 2001, we received approximately \$1,000,000 in proceeds in a private offering of 296,560 shares of common stock at a per share price equal to \$3.37.

Contractual Obligations

Our long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business.

Payments due under contractual obligations at December 31, 2003, are as follows:

	2004	2005	2006	2007	Total
Credit facility with corporate partner ⁽¹⁾	2,436,000	-	-	-	2,436,000
Capital lease obligations ⁽¹⁾	473,000	425,000	238,000	131,000	1,267,000
Operating lease obligations ⁽²⁾	530,000	291,000	28,000	-	849,000
Purchase obligations ⁽³⁾	554,000	-	-	-	554,000
Employment agreements ⁽⁴⁾	1,837,000	1,767,000	-	-	3,604,000
Total	5,830,000	2,483,000	266,000	131,000	8,710,000

(1) See Item 7: "Management's Discussion and Analysis of Financial Condition and Operations - Liquidity and Capital Resources - Secured Revolving Credit Facility and Capital Lease Arrangement".

(2) Operating lease obligations include property rental agreements discussed below.

(3) Purchase obligations include commitments of equipment and services for the enhancement of our manufacturing capabilities for Surfaxin.

(4) See discussion below.

In addition to the contractual obligations above, we have certain milestone payment obligations, aggregating \$2,750,000, and royalty payment obligations to Ortho Pharmaceuticals related to our product licenses.

Operating Lease Obligations

At December 31, 2003, we leased office and laboratory space in Doylestown, Pennsylvania under leases which expire in September 2004, March 2005, and September 2005. Additionally, the Company leased office and laboratory space in Redwood City, California under a lease that expires February 2006, and office space in Windsor, United Kingdom, under a lease which expired December 2003.

Employment Agreements

At December 31, 2003, we had employment agreements with six officers providing for an aggregate annual salary of \$1,440,000. The agreements expire on various dates through December 2005, however, commencing on January 1, 2006, and on each January 1st thereafter, the term of these agreements shall automatically be extended for one additional year, unless at least 90 days prior to such January 1st date, we or the officer shall have given notice that it does not wish to extend the agreement. We also had employment agreements with two other officers that provide for an aggregate annual salary of \$467,000. These agreements expire in December 2005. All of the foregoing agreements provide for the issuance of annual bonuses and the granting of options subject to approval by our Board of Directors.

We will require substantial additional funding to conduct our business, including our expanded research and product development activities. Based on our current operating plan, we believe that our currently available resources, including amounts currently available under our credit facility with PharmaBio, and our capital lease financing arrangement with General Electric Capital Corporation, will be adequate to satisfy our capital needs into 2005. Our future capital

requirements will depend on the results of our research and development activities, clinical studies and trials, competitive and technological advances and the regulatory process. Our operations will not become profitable before we exhaust our current resources; therefore, we will need to raise substantial additional funds through additional debt or equity financings or through collaborative ventures with potential corporate partners. We may in some cases elect to develop products on our own instead of entering into collaboration arrangements and this would increase our cash requirements. Other than our credit facility with PharmaBio and our capital lease financing arrangement with General Electric Capital Corporation, we have not entered into any additional arrangements to obtain any additional financing. The sale of additional equity and debt securities may result in additional dilution to our stockholders, and we cannot be certain that additional financing will be available in amounts or on terms acceptable to us, if at all. If we fail to enter into collaborative ventures or to receive additional funding, we may have to reduce significantly the scope of or discontinue our planned research, development and commercialization activities, which could significantly harm our financial condition and operating results. Furthermore, we could cease to qualify for listing of our common stock on the NASDAQ SmallCap Market if the market price of our common stock declines as a result of the dilutive aspects of such potential financings. See "Risks Related to Our Business – "We will need additional capital, and our ability to continue all of our existing planned research and development activities is uncertain. Any additional financing could result in equity dilution"; " - The market price of our stock may be adversely affected by market volatility"; and " - A substantial number of our securities are eligible for future sale and this could affect the market price for our stock and our ability to raise capital."

Risks Related to Our Business

The following risks, among others, could cause our actual results, performance, achievements or industry results to differ materially from those expressed in our forward-looking statements contained herein and presented elsewhere by management from time to time.

Because we are a biopharmaceutical company, we may not successfully develop and market our products, and even if we do, we may not generate enough revenue or become profitable.

We are a biopharmaceutical company, therefore, you must evaluate us in light of the uncertainties and complexities present in such companies. We currently have no products approved for marketing and sale and are conducting research and development on our product candidates. As a result, we have not begun to market or generate revenues from the commercialization of any of our products. Our long-term viability will be impaired if we are unable to obtain regulatory approval for, or successfully market, our product candidates.

To date, we have only generated revenues from investments, research grants and collaborative research and development agreements. We will need to engage in significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval for our products under development prior to their commercialization. In addition, pre-clinical or clinical studies may show that our products are not effective or safe for one or more of their intended uses. We may fail in the development and commercialization of our products. As of

December 31, 2003, we have an accumulated deficit of approximately \$96,800,000, and we expect to continue to incur significant increasing operating losses over the next several years. If we succeed in the development of our products, we still may not generate sufficient or sustainable revenues or we may not be profitable.

Our technology platform is based solely on our proprietary humanized, engineered surfactant technology. Our ongoing clinical trials for our lead surfactant replacement technologies may be delayed, or fail, which will harm our business.

Our humanized, engineered surfactant platform technology is based on the scientific rationale for surfactant replacement therapy to treat life threatening respiratory disorders and as the foundation for the development of novel respiratory therapies and products. Our business is dependent upon the successful development and approval of our product candidates based on this platform technology. Recently we completed and announced top-line results from a pivotal Phase 3 clinical trial and supportive Phase 3 clinical trial with our lead product, Surfaxin, for the treatment of Respiratory Distress Syndrome in premature infants. In addition, we are conducting a Phase 2 clinical trial for the treatment of Acute Respiratory Distress syndrome in adults and a Phase 3 and a Phase 2 clinical trial for the treatment of Meconium Aspiration Syndrome in full-term infants. We recently completed a Phase 1b clinical trial to evaluate the safety and tolerability of our humanized lung surfactant, delivered as an inhaled aerosol to treat individuals who suffer from asthma.

Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials. Data obtained from tests are susceptible to varying interpretations which may delay, limit or prevent regulatory approval. In addition, we may be unable to enroll patients quickly enough to meet our expectations for completing any or all of these trials. The timing and completion of current and planned clinical trials of our product candidates depend on, among other factors, the rate at which patients are enrolled, which is a function of many factors, including:

- the number of clinical sites;
- the size of the patient population;
- the proximity of patients to the clinical sites;
- the eligibility criteria for the study;
- the existence of competing clinical trials; and
- the existence of alternative available products.

Delays in patient enrollment in clinical trials may occur, which would likely result in increased costs, program delays or both.

We will need additional capital and our ability to continue all of our existing planned research and development activities is uncertain. Any additional financing could result in equity dilution.

We will need substantial additional funding to conduct our presently planned research and product development activities. Based on our current operating plan, we believe that our

currently available financial resources will be adequate to satisfy our capital needs into 2005. Our future capital requirements will depend on a number of factors that are uncertain, including the results of our research and development activities, clinical studies and trials, competitive and technological advances and the regulatory process, among others. We will likely need to raise substantial additional funds through collaborative ventures with potential corporate partners and through additional debt or equity financings. We may also continue to seek additional funding through capital lease transactions. We may in some cases elect to develop products on our own instead of entering into collaboration arrangements. This would increase our cash requirements for research and development.

We have not entered into arrangements to obtain any additional financing, except for the credit facility with PharmaBio and our capital equipment lease financing arrangement with General Electric Capital Corporation. Any additional financing could include unattractive terms or result in significant dilution of stockholders' interests and share prices may decline. If we fail to enter into collaborative ventures or to receive additional funding, we may have to delay, scale back or discontinue certain of our research and development operations, and consider licensing the development and commercialization of products that we consider valuable and which we otherwise would have developed ourselves. If we are unable to raise required capital, we may be forced to limit many, if not all, of our research and development programs and related operations, curtail commercialization of our product candidates and, ultimately, cease operations.

Furthermore, we could cease to qualify for listing of our securities on the NASDAQ SmallCap Market if the market price of our common stock declines as a result of the dilutive aspects of such potential financings. See "Risks Related to Our Business - The market price of our stock may be adversely affected by market volatility."

The clinical trial and regulatory approval process for our products is expensive and time consuming, and the outcome is uncertain.

In order to sell our products that are under development, we must receive regulatory approvals for each product. The FDA and comparable agencies in foreign countries extensively and rigorously regulate the testing, manufacture, distribution, advertising, pricing and marketing of drug products like our products. This approval process includes preclinical studies and clinical trials of each pharmaceutical compound to establish the safety and effectiveness of each product and the confirmation by the FDA and comparable agencies in foreign countries that the manufacturer of the product maintains good laboratory and manufacturing practices during testing and manufacturing. Although we are involved in certain late-stage clinical trials, pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after promising results in earlier clinical trials or in preliminary findings for such clinical trials. Further, even if favorable testing data is generated by clinical trials of drug products, the FDA may not approve a NDA filed by a pharmaceutical or biotechnology company for such drug product.

The approval process is lengthy, expensive and uncertain. It is also possible that the FDA or comparable foreign regulatory authorities could interrupt, delay or halt any one or more of our clinical trials. If we, or any regulatory authorities, believe that trial participants face

unacceptable health risks, any one or more of our trials could be suspended or terminated. We also may not reach agreement with the FDA and/or comparable foreign agencies on the design of any one or more of the clinical studies necessary for approval. Conditions imposed by the FDA and comparable agencies in foreign countries on our clinical trials could significantly increase the time required for completion of such clinical trials and the costs of conducting the clinical trials. Data obtained from clinical trials are susceptible to varying interpretations which may delay, limit or prevent regulatory approval.

Delays and terminations of the clinical trials we conduct could result from insufficient patient enrollment. Patient enrollment is a function of several factors, including the size of the patient population, stringent enrollment criteria, the proximity of the patients to the trial sites, having to compete with other clinical trials for eligible patients, geographical and geopolitical considerations and others. Delays in patient enrollment can result in greater costs and longer trial timeframes. Patients may also suffer adverse medical events or side effects that are common to this class of drug such as a decrease in the oxygen level of the blood upon administration.

Clinical trials generally take two to five years or more to complete, and, accordingly, our first product is not expected to be commercially available in the United States until at least 2005, and our other product candidates will take longer. The FDA has notified us that two of our intended indications for our humanized surfactant-based therapy, Meconium Aspiration Syndrome in full-term infants and Acute Respiratory Distress Syndrome in adults, have been granted designation as "fast-track" products under provisions of the Food and Drug Administration Modernization Act of 1997. The FDA has also granted us Orphan Drug Designation for three of our intended indications for Surfaxin: Acute Respiratory Distress Syndrome in adults; Respiratory Distress Syndrome in infants; and Meconium Aspiration Syndrome in full-term infants. To support our development of Surfaxin for the treatment of Meconium Aspiration Syndrome, the FDA has awarded us an Orphan Products Development Grant. Fast-Track Status does not accelerate the clinical trials nor does it mean that the regulatory requirements are less stringent. The Fast-Track Status provisions are designed to expedite the FDA's review of new drugs intended to treat serious or life-threatening conditions. The FDA generally will review the New Drug Application for a drug granted Fast-Track Status within six months instead of the typical one to three years. Our products may not, however, continue to qualify for expedited review and our other drug candidates may fail to qualify for fast track development or expedited review. Even though some of our drug candidates have qualified for expedited review, the FDA may not approve them at all or any sooner than other drug candidates that do not qualify for expedited review.

The FDA and comparable foreign agencies could withdraw any approvals we obtain, if any. Further, if there is a later discovery of unknown problems or if we fail to comply with other applicable regulatory requirements at any stage in the regulatory process, the FDA may restrict or delay our marketing of a product or force us to make product recalls. In addition, the FDA could impose other sanctions such as fines, injunctions, civil penalties or criminal prosecutions. To market our products outside the United States, we also need to comply with foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products. The FDA and foreign regulators have not yet approved any of our

products under development for marketing in the United States or elsewhere. If the FDA and other regulators do not approve our products, we will not be able to market our products.

In order to conduct our clinical trials we need adequate supplies of our drug substance and drug product and competitor's drug product, which may not be readily available.

To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture. We rely on third party contract manufacturers for our drug substance and other active ingredients for Surfaxin and to produce material that meets appropriate standards for use in clinical trials of our products. We recently transferred our manufacturing capabilities from our single validated clinical manufacturing facility, owned and operated by Akorn to a new contract manufacturer, Laureate, with the objective of producing appropriate clinical grade material of our drug substance that meet the standards for use in our ongoing clinical studies. Laureate may not be able to produce Surfaxin to appropriate standards for use in clinical studies. A failure by Laureate to do so may delay or impair our ability to obtain regulatory approval for Surfaxin. See also "Risks Related to Our Business - If the parties we depend on for manufacturing our pharmaceutical products do not timely supply these products, it may delay or impair our ability to develop and market our products."

If the parties we depend on for manufacturing our pharmaceutical products do not timely supply these products, it may delay or impair our ability to develop and market our products.

We rely on outside manufacturers for our drug substance and other active ingredients for Surfaxin and to produce material that meets appropriate standards for use in clinical studies of our products. Presently, Laureate is our sole clinical manufacturing facility that has been qualified to produce appropriate clinical grade material of our drug substance for use in our ongoing clinical studies.

Laureate or other outside manufacturers may not be able to (i) produce our drug substance to appropriate standards for use in clinical studies, (ii) perform under any definitive manufacturing agreements with us or (iii) remain in the contract manufacturing business for a sufficient time to successfully produce and market our product candidates. If we do not maintain important manufacturing relationships, we may fail to find a replacement manufacturer or develop our own manufacturing capabilities which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and, there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities.

We may in the future elect to manufacture some of our products on our own. Although we own certain specialized manufacturing equipment, are considering an investment in additional manufacturing equipment and employ certain manufacturing managerial personnel, we do not presently maintain a complete manufacturing facility or manufacturing department and we do not anticipate manufacturing on our own any of our products during the next 12 months. If we

decide to manufacture products on our own and do not successfully develop manufacturing capabilities, it will adversely affect sales of our products.

The FDA and foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with current Good Manufacturing Practices (cGMPs) or similar requirements that the FDA or corresponding foreign regulators establish. Manufacturing or quality control problems could occur at the contract manufacturers causing product production and shipment delays or a situation where the contractor may not be able to maintain compliance with the FDA's current cGMP requirements necessary to continue manufacturing our drug substance. Any failure to comply with cGMP requirements or other FDA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to market and develop our products.

Our strategy, in many cases, is to enter into collaboration agreements with third parties with respect to our products and we may require additional collaboration agreements. If we fail to enter into these agreements or if we or the third parties do not perform under such agreements, it could impair our ability to commercialize our products.

Our strategy for the completion of the required development and clinical testing of our products and for the manufacturing, marketing and commercialization of our products, in many cases, depends upon entering into collaboration arrangements with pharmaceutical companies to market, commercialize and distribute our products. We have a collaboration arrangement with Esteve for Surfaxin covering all of Europe and Latin America. Esteve will be responsible for the marketing of Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants and Acute Lung Injury/Acute Respiratory Distress Syndrome in adults. Esteve will also be responsible for the sponsorship of certain clinical trial costs related to obtaining European Medicines Evaluation Agency approval for commercialization of Surfaxin in Europe for the indications of Acute Lung Injury/Acute Respiratory Distress Syndrome. We will be responsible for the remainder of the regulatory activities relating to Surfaxin, including with respect to European Medicines Evaluation Agency filings.

We have entered into an exclusive collaboration arrangement in the United States with Quintiles and PharmaBio to commercialize, sell and market Surfaxin in the United States for indications of Respiratory Distress Syndrome and Meconium Aspiration Syndrome. As part of our collaboration with Quintiles, Quintiles is obligated to build a sales force solely dedicated to the sale of Surfaxin upon the approval of a New Drug Application for either of the two indications. If Quintiles and we fail to devote appropriate resources to commercialize, sell and market Surfaxin, sales of Surfaxin could be reduced. As part of the collaboration, PharmaBio has committed to provide us with certain financial assistance in connection with the commercialization of Surfaxin, including, but not limited to, a secured, revolving credit facility for at least \$8,500,000 which may be increased to \$10,000,000. A failure by us to repay amounts outstanding under the credit facility would have a material adverse effect on us. To obtain the benefits of such financing, we are obligated to meet certain development and performance milestones. The failure by us to meet the milestones or other terms and conditions of the

financing leading to PharmaBio's termination thereof or the failure by PharmaBio to fulfill its obligation to partially fund the commercialization of Surfaxin, may affect our ability to successfully market Surfaxin.

If Esteve, Quintiles, PharmaBio or we breach or terminate the agreements that make up such collaboration arrangements or Esteve, Quintiles or PharmaBio otherwise fail to conduct their Surfaxin-related activities in a timely manner or if there is a dispute about their respective obligations, we may need to seek other partners or we may have to develop our own internal sales and marketing capability for the indications of Surfaxin which Esteve, Quintiles and/or PharmaBio have agreed to assist in commercializing. Accordingly, we may need to enter into additional collaboration agreements and our success, particularly outside of the United States, may depend upon obtaining additional collaboration partners. In addition, we may depend on our partners' expertise and dedication of sufficient resources to develop and commercialize our proposed products. We may, in the future, grant to collaboration partners rights to license and commercialize pharmaceutical products developed under collaboration agreements. Under these arrangements, our collaboration partners may control key decisions relating to the development of the products. The rights of our collaboration partners would limit our flexibility in considering alternatives for the commercialization of our products. If we fail to successfully develop these relationships or if our collaboration partners fail to successfully develop or commercialize any of our products, it may delay or prevent us from developing or commercializing our products in a competitive and timely manner and would have a material adverse effect on the commercialization of Surfaxin. See "Risks Related to Our Business - Our lack of marketing and sales experience could limit our ability to generate revenues from future product sales."

If we cannot protect our intellectual property, other companies could use our technology in competitive products. If we infringe the intellectual property rights of others, other companies could prevent us from developing or marketing our products.

We seek patent protection for our drug candidates so as to prevent others from commercializing equivalent products in substantially less time and at substantially lower expense. The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend in part on our ability and that of parties from whom we license technology to:

- defend our patents and otherwise prevent others from infringing on our proprietary rights;
- protect trade secrets; and
- operate without infringing upon the proprietary rights of others, both in the United States and in other countries.

The patent position of firms relying upon biotechnology is highly uncertain and involves complex legal and factual questions for which important legal principles are unresolved. To date, the United States Patent and Trademark Office has not adopted a consistent policy regarding the breadth of claims that the United States Patent and Trademark Office allows in biotechnology patents or the degree of protection that these types of patents afford. As a result,

there are risks that we may not develop or obtain rights to products or processes that are or may seem to be patentable.

Even if we obtain patents to protect our products, those patents may not be sufficiently broad and others could compete with us.

We, and the parties licensing technologies to us, have filed various United States and foreign patent applications with respect to the products and technologies under our development, and the United States Patent and Trademark Office and foreign patent offices have issued patents with respect to our products and technologies. These patent applications include international applications filed under the Patent Cooperation Treaty. Our pending patent applications, those we may file in the future or those we may license from third parties may not result in the United States Patent and Trademark Office or foreign patent office issuing patents. Also, if patent rights covering our products are not sufficiently broad, they may not provide us with sufficient proprietary protection or competitive advantages against competitors with similar products and technologies. Furthermore, if the United States Patent and Trademark Office or foreign patent offices issue patents to us or our licensors, others may challenge the patents or circumvent the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from or to third parties may not provide any protection against competitors.

Furthermore, the life of our patents is limited. We have licensed a series of patents from Johnson & Johnson and Ortho Pharmaceutical which are important, either individually or collectively, to our strategy of commercializing our surfactant technology. Such patents, which include relevant European patents, expire on various dates beginning in 2009 and ending in 2017 or, in some cases, possibly later. We have filed, and when possible and appropriate, will file, other patent applications with respect to our products and processes in the United States and in foreign countries. We may not be able to develop additional products or processes that will be patentable or additional patents may not be issued to us. See also "Risks Related to Our Business - If we cannot meet requirements under our license agreements, we could lose the rights to our products."

Intellectual property rights of third parties could limit our ability to market our products.

Our commercial success also significantly depends on our ability to operate without infringing the patents or violating the proprietary rights of others. The United States Patent and Trademark Office keeps United States patent applications confidential while the applications are pending. As a result, we cannot determine which inventions third parties claim in pending patent applications that they have filed. We may need to engage in litigation to defend or enforce our patent and license rights or to determine the scope and validity of the proprietary rights of others. It will be expensive and time consuming to defend and enforce patent claims. Thus, even in those instances in which the outcome is favorable to us, the proceedings can result in the diversion of substantial resources from our other activities. An adverse determination may subject us to significant liabilities or require us to seek licenses that third parties may not grant to us or may only grant at rates that diminish or deplete the profitability of the products to us. An adverse determination could also require us to alter our products or processes or cease altogether any related research and development activities or product sales.

If we cannot meet requirements under our license agreements, we could lose the rights to our products.

We depend on licensing agreements with third parties to maintain the intellectual property rights to our products under development. Presently, we have licensed rights from Johnson & Johnson and Ortho Pharmaceutical. These agreements require us to make payments and satisfy performance obligations in order to maintain our rights under these licensing agreements. All of these agreements last either throughout the life of the patents, or with respect to other licensed technology, for a number of years after the first commercial sale of the relevant product.

In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under our license agreements in a timely manner, we could lose the rights to our proprietary technology.

In addition, we may be required to obtain licenses to patents or other proprietary rights of third parties in connection with the development and use of our products and technologies. Licenses required under any such patents or proprietary rights might not be made available on terms acceptable to us, if at all.

We rely on confidentiality agreements that could be breached and may be difficult to enforce.

Although we believe that we take reasonable steps to protect our intellectual property, including the use of agreements relating to the non-disclosure of confidential information to third parties, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees and consultants while we employ them, the agreements can be difficult and costly to enforce. Although we seek to obtain these types of agreements from our consultants, advisors and research collaborators, to the extent that they apply or independently develop intellectual property in connection with any of our projects, disputes may arise as to the proprietary rights to this type of information. If a dispute arises, a court may determine that the right belongs to a third party, and enforcement of our rights can be costly and unpredictable. In addition, we will rely on trade secrets and proprietary know-how that we will seek to protect in part by confidentiality agreements with our employees, consultants, advisors or others. Despite the protective measures we employ, we still face the risk that:

- they will breach these agreements;
- any agreements we obtain will not provide adequate remedies for the applicable type of breach or that our trade secrets or proprietary know-how will otherwise become known or competitors will independently develop similar technology; and
- our competitors will independently discover our proprietary information and trade secrets.

Our lack of marketing and sales experience could limit our ability to generate revenues from future product sales.

We do not have marketing, sales or distribution experience or marketing or sales personnel. As a result, we will depend on our collaboration with Quintiles for the marketing and sales of Surfaxin for indications of Respiratory Distress Syndrome in premature infants and Meconium Aspiration Syndrome in full-term infants in the United States and with Esteve for the marketing and sales of Surfaxin for the treatment of Respiratory Distress Syndrome, Meconium Aspiration Syndrome and Acute Lung Injury/Acute Respiratory Distress Syndrome in adult patients in all of Europe and Latin America. See "Risks Related to Our Business - Our strategy, in many cases, is to enter into collaboration agreements with third parties with respect to our products and we may require additional collaboration agreements. If we fail to enter into these agreements or if we or the third parties do not perform under such agreements, it could impair our ability to commercialize our products." If we do not develop a marketing and sales force of our own, then we will depend on arrangements with corporate partners or other entities for the marketing and sale of our remaining products.

The sales and marketing of Surfaxin for indications of Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants and Acute Lung Injury/Acute Respiratory Distress Syndrome in adult patients in the relevant territories depends, in part, on Quintiles', PharmaBio's and Esteve's performance of their contractual obligations. The failure of either party to do so would have a material adverse effect on the sales and marketing of Surfaxin. We may not succeed in entering into any satisfactory third party arrangements with terms acceptable to us, if at all, for the marketing and sale of our remaining products. In addition, we may not succeed in developing marketing and sales capabilities, our commercial launch of certain products may be delayed until we establish marketing and sales capabilities or we may not have sufficient resources to do so. If we fail to establish marketing and sales capabilities or fail to enter into arrangements with third parties, either in a timely manner, it will adversely affect sales of our products.

We depend upon key employees and consultants in a competitive market for skilled personnel. If we are unable to attract and retain key personnel, it could adversely affect our ability to develop and market our products.

We are highly dependent upon the principal members of our management team, especially our Chief Executive Officer, Dr. Capetola, and our directors, as well as our scientific advisory board members, consultants and collaborating scientists. Many of these people have been involved in our formation or have otherwise been involved with us for many years, have played integral roles in our progress and we believe that they will continue to provide value to us. A loss of any of these personnel may have a material adverse effect on aspects of our business and clinical development and regulatory programs. We have an employment agreement with Dr. Capetola that expires on December 31, 2005. We also have employment agreements with other key personnel with termination dates from 2004 through 2005. Although these employment agreements generally provide for severance payments that are contingent upon the applicable employee's refraining from competition with us, the loss of any of these persons' services would adversely affect our ability to develop and market our products and obtain necessary regulatory

approvals, and the applicable noncompete provisions can be difficult and costly to monitor and enforce. Further, we do not maintain key-man life insurance.

Our future success also will depend in part on the continued service of our key scientific and management personnel and our ability to identify, hire and retain additional personnel, including marketing and sales staff. We experience intense competition for qualified personnel, and the existence of non-competition agreements between prospective employees and their former employers may prevent us from hiring those individuals or subject us to suit from their former employers.

While we attempt to provide competitive compensation packages to attract and retain key personnel, some of our competitors are likely to have greater resources and more experience than we have, making it difficult for us to compete successfully for key personnel.

Our industry is highly competitive and we have less capital and resources than many of our competitors, which may give them an advantage in developing and marketing products similar to ours or make our products obsolete.

Our industry is highly competitive and subject to rapid technological innovation and evolving industry standards. We compete with numerous existing companies intensely in many ways. We intend to market our products under development for the treatment of diseases for which other technologies and treatments are rapidly developing and, consequently, we expect new companies to enter our industry and that competition in the industry will increase. Many of these companies have substantially greater research and development, manufacturing, marketing, financial, technological, personnel and managerial resources than we have. In addition, many of these competitors, either alone or with their collaborative partners, have significantly greater experience than we do in:

- developing products;
- undertaking preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals or products; and
- manufacturing and marketing products.

Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA or comparable foreign approval or commercializing products before us. If we commence commercial product sales, we will compete against companies with greater marketing and manufacturing capabilities who may successfully develop and commercialize products that are more effective or less expensive than ours. These are areas in which, as yet, we have limited or no experience. In addition, developments by our competitors may render our product candidates obsolete or noncompetitive.

Presently, there are no approved drugs that are specifically indicated for the treatment of Meconium Aspiration Syndrome in full-term infants or Acute Lung Injury/Acute Respiratory Distress Syndrome in adults. Current therapy consists of general supportive care and mechanical ventilation.

Four products, three that are animal-derived and one that is a synthetic, are specifically approved for the treatment of Respiratory Distress Syndrome in premature infants. Exosurf® is synthetic and is marketed by GlaxoSmithKline, plc, outside the United States and contains only phospholipids (the fats normally present in the lungs) and synthetic organic detergents and no stabilizing protein or peptides. This product, however, does not contain any surfactant proteins, is not widely used and its active marketing recently has been discontinued by its manufacturer. Curosurf® is a porcine lung extract that is marketed in Europe by Chiesi Farmaceutici S.p.A., and in the United States by Dey Laboratories, Inc. Survanta®, marketed by the Ross division of Abbott Laboratories, Inc., is an extract of bovine lung that contains the cow version of surfactant protein C. Forest Laboratories, Inc., markets its calf lung surfactant, Infasurf® in the United States for the treatment of Respiratory Distress Syndrome in premature infants. Although none of the four approved surfactants for Respiratory Distress Syndrome in premature infants is approved for Acute Lung Injury or Acute Respiratory Distress Syndrome in adults, which are significantly larger markets, there are a significant number of other potential therapies in development for these indications that are not surfactant-related. Any of these various drugs or devices could significantly impact the commercial opportunity for Surfaxin. We believe that engineered humanized surfactants such as Surfaxin will be far less expensive to produce than the animal-derived products approved for the treatment of Respiratory Distress Syndrome in premature infants and will have no capability of transmitting the brain-wasting bovine spongiform encephalopathy (commonly called “mad-cow disease”) or causing adverse immunological responses in young and older adults.

We also face, and will continue to face, competition from colleges, universities, governmental agencies and other public and private research organizations. These competitors are becoming more active in seeking patent protection and licensing arrangements to collect royalties for use of technology that they have developed. Some of these technologies may compete directly with the technologies that we are developing. These institutions will also compete with us in recruiting highly qualified scientific personnel. We expect that therapeutic developments in the areas in which we are active may occur at a rapid rate and that competition will intensify as advances in this field are made. As a result, we need to continue to devote substantial resources and efforts to research and development activities.

If product liability claims are brought against us, it may result in reduced demand for our products or damages that exceed our insurance coverage.

The clinical testing of, marketing and use of our products exposes us to product liability claims in the event that the use or misuse of those products causes injury, disease or results in adverse effects. Use of our products in clinical trials, as well as commercial sale, could result in product liability claims. In addition, sales of our products through third party arrangements could also subject us to product liability claims. We presently carry product liability insurance with coverages of up to \$10,000,000 per occurrence and \$10,000,000 in the aggregate, an amount we consider reasonable and customary relating to our clinical trials of Surfaxin. However, this insurance coverage includes various deductibles, limitations and exclusions from coverage, and in any event might not fully cover any potential claims. We may need to obtain additional product liability insurance coverage prior to initiating other clinical trials. We expect to obtain product liability insurance coverage before commercialization of our proposed products;

however, the insurance is expensive and insurance companies may not issue this type of insurance when we need it. We may not be able to obtain adequate insurance in the future at an acceptable cost. Any product liability claim, even one that was not in excess of our insurance coverage or one that is meritless and/or unsuccessful, could adversely affect our cash available for other purposes, such as research and development. In addition, the existence of a product liability claim could affect the market price of our common stock.

We expect to face uncertainty over reimbursement and healthcare reform.

In both the United States and other countries, sales of our products will depend in part upon the availability of reimbursement from third party payors, which include government health administration authorities, managed care providers and private health insurers. Third party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services.

Directors, executive officers, principal stockholders and affiliated entities own a significant percentage of our capital stock, and they may make decisions that you do not consider to be in your best interest.

As of December 31, 2003, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately 15% of our outstanding voting securities. As a result, if some or all of them acted together, they would have the ability to exert substantial influence over the election of our Board of Directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may have the effect of delaying or preventing a change in control of our Company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

The market price of our stock may be adversely affected by market volatility.

The market price of our common stock, like that of many other development stage pharmaceutical or biotechnology companies, has been and is likely to be volatile. In addition to general economic, political and market conditions, the price and trading volume of our stock could fluctuate widely in response to many factors, including:

- announcements of the results of clinical trials by us or our competitors;
- adverse reactions to products;
- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;
- changes in the United States or foreign regulatory policy during the period of product development;
- developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- announcements of technological innovations by us or our competitors;
- announcements of new products or new contracts by us or our competitors;

- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
- conditions and trends in the pharmaceutical and other industries;
- new accounting standards; and
- the occurrence of any of the risks described in this “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Risks Related to Our Business.”

Our common stock is listed for quotation on the NASDAQ SmallCap Market. For the 12-month period ended December 31, 2003, the price of our common stock has ranged from \$1.32 to \$10.75. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. For the 12-month period ended December 31, 2003, the average daily trading volume in our common stock was approximately 401,301 shares and the average number of transactions per day was approximately 735. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

In addition, we may not be able to continue to adhere to the strict listing criteria of the SmallCap Market. If the common stock were no longer listed on the SmallCap Market, investors might only be able to trade in the over-the-counter market in the Pink Sheets[®] (a quotation medium operated by the National Quotation Bureau, LLC) or on the OTC Bulletin Board[®] of the National Association of Securities Dealers, Inc. This would impair the liquidity of our securities not only in the number of shares that could be bought and sold at a given price, which might be depressed by the relative illiquidity, but also through delays in the timing of transactions and reduction in media coverage.

In the past, following periods of volatility in the market price of the securities of companies in our industry, securities class action litigation has often been instituted against companies in our industry. If we face securities litigation in the future, even if meritless or unsuccessful, it would result in substantial costs and a diversion of management attention and resources, which would negatively impact our business.

A substantial number of our securities are eligible for future sale and this could affect the market price for our stock and our ability to raise capital.

The market price of our common stock could drop due to sales of a large number of shares of our common stock or the perception that these sales could occur. As of December 31, 2003, we had 42,491,438 shares of common stock outstanding. In addition, as of December 31, 2003, up to approximately 8,753,000 shares of our common stock were issuable upon exercise of outstanding options and warrants. On December 19, 2003, we filed a Form S-3 shelf registration statement with the Commission for the proposed offering from time to time of up to 6,500,000 shares of common stock. We have no immediate plans to sell any securities under the shelf registration. However, as the registration statement has been declared effective by the Commission, we may

issue securities from time to time in response to market conditions or other circumstances on terms and conditions that will be determined at such time.

Holders of our stock options and warrants are likely to exercise them, if ever, at a time when we otherwise could obtain a price for the sale of our securities that is higher than the exercise price per security of the options or warrants. This exercise, or the possibility of this exercise, may impede our efforts to obtain additional financing through the sale of additional securities or make this financing more costly, and may reduce the price of our common stock.

Provisions of our Certificate of Incorporation, Shareholders Rights Agreement and Delaware law could defer a change of our management which could discourage or delay offers to acquire us.

Provisions of our Certificate of Incorporation, Shareholders Rights Agreement and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in management would be beneficial to our stockholders. For example, our Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In addition, our Board of Directors, without further stockholder approval, could issue large blocks of preferred stock. We have adopted a shareholders rights agreement which under certain circumstances would significantly impair the ability of third parties to acquire control of us without prior approval of our Board of Directors thereby discouraging unsolicited takeover proposals. The rights issued under the shareholders rights agreement would cause substantial dilution to a person or group that attempts to acquire us on terms not approved in advance by our Board of Directors.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is confined to our cash, cash equivalents and available for sale securities. We place our investments with high quality issuers and, by policy, limit the amount of credit exposure to any one issuer. We currently do not hedge interest rate or currency exchange exposure. We classify highly liquid investments purchased with a maturity of three months or less as "cash equivalents" and commercial paper and fixed income mutual funds as "available for sale securities." Fixed income securities may have their fair market value adversely affected due to a rise in interest rates and we may suffer losses in principal if forced to sell securities that have declined in market value due to a change in interest rates.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

See Index to Consolidated Financial Statements on Page F-1.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

Not Applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Our Chief Executive Officer, Chief Operating Officer, Chief Financial Officer and Chief Accounting Officer, after evaluating the effectiveness of our “disclosure controls and procedures” (as defined in Rules 13a-14(c) and 15d-14(c) of the Securities Exchange Act of 1934) as of the end of the fiscal year ended December 31, 2003, have concluded that as of the time of such evaluation, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in this annual report is accumulated and communicated by our management, to allow timely decisions regarding required disclosure.

There were no significant changes in our internal controls or other factors that could significantly affect our disclosure controls and procedures subsequent to the date of their evaluation and there were no corrective actions with regard to significant deficiencies and material weaknesses.

PART III

The information required by Items 10 through 14 of Part III is incorporated by reference to our definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the end of our fiscal year.

We have adopted a Code of Ethics that applies to our officers, including our principal executive, financial and accounting officers, and our directors and employees. We have posted the Code of Ethics on our Internet Website at “<http://www.DiscoveryLabs.com>” (this is not a hyperlink, you must visit this website through an Internet browser) under the Legal section. We intend to make all required disclosures on a Current Report on Form 8-K concerning any amendments to, or waivers from, our Code of Ethics with respect to our executive officers and directors. Our Website and the information contained therein or connected thereto are not incorporated into this Annual Report on Form 10-K.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K.

(a) Exhibits

Exhibits are listed on the Index to Exhibits at the end of this Annual Report. The exhibits required by Item 601 of Regulation S-K, listed on such Index in response to this Item, are incorporated herein by reference.

(b) Reports on Form 8-K

We filed three Current Reports on Form 8-K during the three months ended December 31, 2003. We filed a Current Report on October 22, 2003, reporting the initiation of a Technology Transfer and Manufacturing Agreement with Laureate as part of the manufacturing facility transfer from Akorn to Laureate. We filed a Current Report on November 25, 2003, reporting positive primary endpoint results from the pivotal, multinational, landmark phase 3 superiority clinical trial of Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants. We filed a Current Report on December 19, 2003, reporting the filing of a Form S-3 shelf registration statement with the Commission for the proposed offering from time to time of up to 6,500,000 shares of our common stock.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

DISCOVERY LABORATORIES, INC.

Date: March 15, 2004

By: /s/ Robert J. Capetola
Robert J. Capetola, Ph.D.
President and
Chief Executive Officer

In accordance with the Exchange Act, this Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Name & Title</u>	<u>Date</u>
<u>/s/ Robert J. Capetola</u>	Robert J. Capetola, Ph.D. President and Chief Executive Officer	March 15, 2004
<u>/s/ John G. Cooper</u>	John G. Cooper Executive Vice President and Chief Financial Officer	March 15, 2004
<u>/s/ Cynthia Davis</u>	Cynthia Davis Vice President, Administrative Operations and Controller (Principal Accounting Officer)	March 15, 2004
<u>/s/ Herbert H. McDade, Jr.</u>	Herbert H. McDade, Jr. Chairman of the Board of Directors	March 15, 2004
<u>/s/ Marvin E. Rosenthale</u>	Marvin E. Rosenthale, Ph.D. Director	March 15, 2004
<u>/s/ Max E. Link</u>	Max E. Link, Ph.D. Director	March 15, 2004
<u>/s/ Antonio Esteve</u>	Antonio Esteve, Ph.D. Director	March 15, 2004

EXHIBIT INDEX

EXHIBIT NO.

DESCRIPTION

3.1 ⁽¹⁶⁾	Restated Certificate of Incorporation of Discovery, dated September 18, 2002.
3.2*	Amended and Restated By-laws of Discovery, as of December 12, 2003.
4.1 ⁽⁷⁾	Class E Warrant issued to PharmaBio.
4.2 ⁽⁸⁾	Unit Purchase Option issued to Paramount Capital, Inc., in connection with the March 1999 private placement.
4.3 ⁽¹¹⁾	Form of Class G Warrant issued to PharmaBio.
4.4 ⁽¹⁾	Form of Class H Warrant issued to PharmaBio.
4.5 ⁽¹¹⁾	Form of Promissory Note issued to PharmaBio.
4.6 ⁽¹⁶⁾	Promissory Note issued to General Electric Capital Corporation.
4.7 ⁽¹⁷⁾	Form of Class A Investor Warrant.
10.1 ⁽¹⁾	Registration Rights Agreement, dated as of October 28, 1996, between ATI, Johnson & Johnson Development Corporation and The Scripps Research Institute.
10.2 ⁽³⁾⁺	Sublicense Agreement, dated as of October 28, 1996, between ATI, Johnson & Johnson, Inc., and Ortho Pharmaceutical Corporation.
10.3 ⁽²⁾	Restated 1993 Stock Option Plan of Discovery.
10.4 ⁽²⁾	1995 Stock Option Plan of Discovery.
10.5 ⁽¹⁸⁾	Amended and Restated 1998 Stock Incentive Plan of Discovery (amended as of July 15, 2003).
10.6 ⁽⁵⁾	Indenture of Lease, dated as of July 1, 1998, between SLT1, LLC and Discovery.
10.7 ⁽¹⁰⁾	Amendment, dated as of September 15, 2000, to the Indenture of Lease dated as of July 1, 1998, between SLT1, LLC and Discovery.
10.8 ⁽⁵⁾	Registration Rights Agreement, dated as of June 16, 1998, among Discovery, JJDC and Scripps.

- 10.9⁽⁵⁾ Stock Exchange Agreement, dated as of June 16, 1998, between Discovery and JJDC.
- 10.10⁽¹⁰⁾ Employment Agreement, dated January 1, 2001, between Discovery and Robert J. Capetola, Ph.D.
- 10.11⁽¹⁴⁾ Employment Agreement, dated as of June 16, 2001, between Discovery and Christopher J. Schaber.
- 10.12⁽¹⁴⁾ Employment Agreement, dated as of June 16, 2001, between Discovery and Cynthia Davis.
- 10.13⁽⁵⁾ Form of Intellectual Property and Confidential Information Agreement.
- 10.14⁽⁵⁾ Form of Stock Purchase Agreement Under the 1998 Stock Incentive Plan of Discovery.
- 10.15⁽⁶⁾ Form of Notice of Grant of Stock Option.
- 10.16⁽⁸⁾ Securities Purchase Agreement between Discovery and Laboratorios P.E.N., S.A., dated October 26, 1999.
- 10.17⁽⁸⁾⁺ Research Funding and Option Agreement, dated as of March 1, 2000, between Discovery and Scripps.
- 10.18⁽¹⁴⁾ Employment Agreement, dated as of December 1, 2001, between Discovery and Ralph Niven, Ph.D.
- 10.19⁽¹⁴⁾ Employment Agreement, dated as of December 11, 2001, between Discovery and John G. Cooper.
- 10.20⁽¹⁴⁾ Employment Agreement, dated as of August 15, 2000, between Discovery and Deni M. Zodda, Ph.D.
- 10.21⁽¹²⁾⁺ Commercialization Agreement, dated as of December 10, 2001, between Discovery and Quintiles.
- 10.22⁽¹²⁾⁺ Investment and Commission Agreement, dated as of December 10, 2001, between Discovery and PharmaBio.
- 10.23⁽¹²⁾ Common Stock and Warrant Purchase Agreement, dated as of December 10, 2001, between Discovery and PharmaBio.

- 10.24⁽¹²⁾+ Loan Agreement, dated as of December 10, 2001, between Discovery and PharmaBio.
- 10.25⁽¹³⁾+ Sublicense and Collaboration Agreement, dated as of March 6, 2002, between Discovery and Laboratorios del Dr. Esteve.
- 10.26⁽¹³⁾+ Supply Agreement, dated as of March 6, 2002, between Discovery and Esteve.
- 10.27⁽¹³⁾ Common Stock Purchase Agreement, dated as of March 6, 2002, between Discovery and Esteve.
- 10.28⁽¹⁵⁾ Form of Common Stock and Warrant Purchase Agreement, dated November 5, 2002, between Discovery and certain investors.
- 10.29⁽¹⁶⁾ Master Security Agreement, dated December 23, 2002, between Discovery and General Electric Capital Corporation.
- 10.30⁽¹⁶⁾ Amendment, dated December 23, 2003, to the Master Security Agreement between Discovery and General Electric Capital Corporation.
- 10.31⁽¹⁹⁾+ Technology Transfer and Manufacturing Agreement dated as of October 13, 2003, between Discovery and Laureate Pharma, L.P.
- 16.1⁽⁴⁾ Letter dated as of January 28, 1998, from Ernst & Young LLP to the Securities and Exchange Commission.
- 16.2⁽⁹⁾ Letter dated January 9, 2001, from Eisner LLP, to the Securities and Exchange Commission.
- 21.1⁽¹⁾ Subsidiaries of Discovery.
- 23.1* Consent of Ernst & Young LLP.
- 31.1* Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) of the Exchange Act.
- 31.2* Certification of Chief Financial Officer and Principal Accounting Officer Pursuant to Rule 13a-14(a) of the Exchange Act.
- 32.1* Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* filed herewith

- (1) Incorporated by reference to Discovery's Annual Report on Form 10-KSB for the year ending December 31, 1997.
- (2) Incorporated by reference to Discovery's Registration Statement on Form SB-2 (File No. 33-92-886).
- (3) Incorporated by reference to Discovery's Registration Statement on Form SB-2 (File No. 333-19375).
- (4) Incorporated by reference to Discovery's Current Report on Form 8-K/A dated January 16, 1998.
- (5) Incorporated by reference to Discovery's Annual Report on Form 10-KSB for the year ending December 31, 1998.
- (6) Incorporated by reference to Discovery's Quarterly Report on Form 10-QSB for the quarter ending September 30, 1999.
- (7) Incorporated by reference to Discovery's Current Report on Form 8-K filed March 29, 2000.
- (8) Incorporated by reference to Discovery's Annual Report on Form 10-KSB for the year ending December 31, 1999.
- (9) Incorporated by reference to Discovery's Amended Current Report on Form 8-K/A filed January 9, 2001.
- (10) Incorporated by reference to Discovery's Annual Report on Form 10-KSB for the year ending December 31, 2000.
- (11) Incorporated by Reference to Discovery's Current Report on Form 8-K filed December 19, 2001.
- (12) Incorporated by Reference to Discovery's Amended Current Report on Form 8-K/A filed January 14, 2002.
- (13) Incorporated by Reference to Discovery's Current Report on Form 8-K filed March 8, 2002.
- (14) Incorporated by Reference to Discovery's Annual Report on Form 10-KSB for the year ending December 31, 2001.
- (15) Incorporated by Reference to Discovery's Current Report on Form 8-K filed November 12, 2002.

- (16) Incorporated by Reference to Discovery's Annual Report on Form 10-K for the year ending December 31, 2002.
- (17) Incorporated by Reference to Discovery's Current Report on Form 8-K filed June 30, 2003.
- (18) Incorporated by reference to Discovery's Registration Statement on Form S-8 (File No. 333-109274).
- (19) Incorporated by Reference to Discovery's Current Report on Form 8-K filed October 22, 2003.

+ Confidential treatment requested as to certain portions of these exhibits. Such portions have been redacted and filed separately with the Commission.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

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REPORT OF INDEPENDENT AUDITORS

Board of Directors and Stockholders
Discovery Laboratories, Inc.
Doylestown, Pennsylvania

We have audited the accompanying consolidated balance sheets of Discovery Laboratories, Inc. as of December 31, 2003, and 2002, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Discovery Laboratories, Inc. at December 31, 2003, and 2002, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
February 13, 2004

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Balance Sheets

	December 31, 2003	December 31, 2002
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 29,422,000	\$ 8,500,000
Available-for-sale marketable securities	—	10,652,000
Note receivable - current	3,000	2,000
Prepaid expenses and other current assets	665,000	325,000
Total current assets	30,090,000	19,479,000
Property and equipment, net of accumulated depreciation	2,414,000	1,231,000
Note receivable	192,000	195,000
Other assets	19,000	157,000
Total Assets	<u>\$ 32,715,000</u>	<u>\$ 21,062,000</u>
LIABILITIES & STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 4,210,000	\$ 3,013,000
Credit facility with corporate partner – current portion	2,436,000	—
Capitalized lease – current portion	383,000	189,000
Total current liabilities	7,029,000	3,202,000
Deferred revenue	672,000	1,393,000
Credit facility with corporate partner	—	1,450,000
Capitalized lease, net of current portion	711,000	256,000
Total Liabilities	8,412,000	6,301,000
Shareholders' equity:		
Common stock, \$.001 par value; 60,000,000 authorized; 42,491,438 and 32,818,283 issued and outstanding at December 31, 2003 and December 31, 2002, respectively	43,000	33,000
Additional paid-in capital	122,409,000	87,463,000
Unearned portion of compensatory stock options	(2,000)	(95,000)
Accumulated deficit	(96,858,000)	(72,578,000)
Treasury stock (at cost; 167,179 and 38,243 shares of common stock at December 31, 2003, and 2002)	(1,289,000)	(239,000)
Accumulated other comprehensive income	—	177,000
Total shareholders' equity	24,303,000	14,761,000
Total Liabilities & Equity	<u>\$ 32,715,000</u>	<u>\$ 21,062,000</u>

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Operations

	Year Ended December 31,		
	2003	2002	2001
Revenues:			
Contracts, Licensing, Milestones and Grants	\$ 1,037,000	\$ 1,782,000	\$ 1,112,000
Expenses:			
Research & Development	19,750,000	14,347,000	8,007,000
General & Administrative	5,722,000	5,458,000	5,067,000
Total Expenses	<u>25,472,000</u>	<u>19,805,000</u>	<u>13,074,000</u>
Operating Loss	(24,435,000)	(18,023,000)	(11,962,000)
Other income and expenses:			
Interest income, dividends, realized gains, and other income	452,000	724,000	842,000
Interest expense	<u>(297,000)</u>	<u>(144,000)</u>	<u>(26,000)</u>
Net Loss	<u>\$ (24,280,000)</u>	<u>\$ (17,443,000)</u>	<u>\$ (11,146,000)</u>
Net loss per common share - basic and diluted	\$ (0.65)	\$ (0.64)	\$ (0.51)
Weighted average number of common shares outstanding - basic and diluted	37,426,034	27,350,835	22,038,067

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Changes in Stockholders' Equity For Years Ended December 31, 2003, 2002, and 2001

	Common Stock	Additional Paid-in Capital	Unearned Portion of Compensatory Stock Options	Accumulated Deficit	Treasury Stock	Accumulated Other Comprehensive Loss	Total
	Shares	Amount			Shares	Amount	
Balance - January 1, 2001	20,871,112	\$ 21,000	\$ 60,891,000	\$ (347,000)	\$ (41,989,000)	\$ (213,000)	\$ 16,436,000
Comprehensive loss:							
Net loss							(11,146,000)
Other comprehensive loss - unrealized loss on marketable securities available-for-sale							(1,000)
Total comprehensive loss							(11,147,000)
Exercise of stock options	6,224	2,000					42,000
Common Stock issued in payment for services	10,902	42,000					109,000
Compensatory charge on modification of options		100,000					408,000
Compensatory stock options and warrants granted/earned		325,000	83,000				998,000
Common Stock issued in April 2001 private financing	296,560						7,256,000
Common Stock and warrants issued in October 2001 private financing	3,562,759	4,000					3,540,000
Common Stock and warrants issued in December 2001	791,905	1,000					
Placement agent warrant exercise	6,831						
Purchase of Treasury Stock					(11,500)	(26,000)	
Balance - December 31, 2001	25,546,293	26,000	73,163,000	(55,135,000)	(38,243)	(239,000)	17,623,000
Comprehensive loss:							
Net loss							(17,443,000)
Other comprehensive loss - unrealized gain on marketable securities available-for-sale							105,000
Total comprehensive loss							(17,338,000)
Exercise of stock options	77,925	60,000					26,000
Common Stock issued in lieu of payment for services	6,086	26,000					171,000
Compensation charge on modification of options		171,000					232,000
Compensation charge on vesting of options and warrants		63,000	169,000				2,666,000
Common Stock issued in March 2002 private financing	821,862						(5,000)
Private financing expenses		(5,000)					11,944,000
Common Stock issued in November 2002 private financing	6,397,517	7,000					(618,000)
Change in value of Class H warrants							
Exercise of warrants	6,843						
Balance - December 31, 2002	32,856,526	33,000	87,463,000	(95,000)	(72,578,000)	(239,000)	14,761,000
Comprehensive loss:							
Net loss							(24,280,000)
Other comprehensive loss - unrealized loss on marketable securities available-for-sale							(177,000)
Total comprehensive loss							(24,457,000)
Exercise of stock options	993,001	1,000					1,941,000
Exercise of warrants	3,789,875	4,000					6,850,000
Compensatory stock options and warrants granted/earned							3,000
Compensation charge on modification of options		20,000	(17,000)				75,000
Compensation charge on vesting of options and warrants		79,000	25,000				104,000
Earned portion of compensatory stock options			10,000				25,930,000
Common Stock issued in June 2003 private financing	4,997,882	5,000					86,000
Common Stock issued in 401k Match	21,333						50,000
Change in value of Class H warrants					(128,936)	(1,050,000)	
Purchase of Treasury Stock					(167,179)		
Balance - December 31, 2003	42,658,617	\$ 43,000	\$ 122,409,000	\$ (2,000)	\$ (96,858,000)	\$ (1,289,000)	\$ 24,303,000

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Cash Flows

	Year Ended December 31,		
	2003	2002	2001
Cash flow from operating activities:			
Net loss	\$ (24,280,000)	\$ (17,443,000)	\$ (11,146,000)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	416,000	285,000	205,000
Realized (gains) losses on marketable securities	(114,000)	(174,000)	55,000
Compensatory stock options	192,000	403,000	517,000
Stock issued in 401(k) match	86,000	—	—
Expenses paid using treasury stock and Common Stock	—	26,000	42,000
Changes in:			
Prepaid expenses, inventory and other current assets	(340,000)	1,255,000	(876,000)
Accounts payable and accrued expenses	1,197,000	1,263,000	(632,000)
Other assets	103,000	(40,000)	(18,000)
Proceeds from research and development collaborative agreements	—	1,833,000	—
Amortization of deferred revenue	(721,000)	(1,055,000)	(791,000)
Net cash used in operating activities	(23,461,000)	(13,647,000)	(12,644,000)
Cash flow from investing activities:			
Purchase of property and equipment	(606,000)	(227,000)	(257,000)
Loan to related party	—	—	(200,000)
Related party loan payments received	2,000	2,000	1,000
Purchase of marketable securities	(284,000)	(8,569,000)	(10,676,000)
Proceeds from sale or maturity of marketable securities	10,873,000	11,134,000	9,269,000
Net cash provided by (used in) investing activities	9,985,000	2,340,000	(1,863,000)
Cash flow from financing activities:			
Proceeds from issuance of securities, net of expenses	34,721,000	14,665,000	11,033,000
Proceeds from credit facility with corporate partner	986,000	1,450,000	—
Purchase of treasury stock	(1,050,000)	—	(26,000)
Principal payments under capital lease obligation	(259,000)	(66,000)	(23,000)
Net cash provided by financing activities	34,398,000	16,049,000	10,984,000
<u>Net increase (decrease) in cash and cash equivalents</u>	<u>20,922,000</u>	<u>4,742,000</u>	<u>(3,523,000)</u>
Cash and cash equivalents – beginning of year	8,500,000	3,758,000	7,281,000
<u>Cash and cash equivalents – end of year</u>	<u>\$ 29,422,000</u>	<u>\$ 8,500,000</u>	<u>\$ 3,758,000</u>
Supplementary disclosure of cash flows information:			
Interest Paid	\$ 167,000	\$ 88,000	\$ 26,000
Noncash transactions:			
Class H warrants issued/revalued	\$ 50,000	\$ (618,000)	\$ 768,000
Equipment acquired through capitalized lease	908,000	434,000	52,000
Unrealized gain (loss) on marketable securities	(177,000)	105,000	(1,000)

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Notes to Consolidated Financial Statements

December 31, 2003

Note 1 – The Company and Basis of Presentation

Discovery Laboratories, Inc. is a biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies for respiratory diseases including Respiratory Distress Syndromes in infants and adults, Acute Lung Injury, asthma, Chronic Obstructive Pulmonary Disease and upper airway disorders. Surfactants are compositions produced naturally in the lungs and essential for breathing. Discovery's technology produces an engineered version of natural human lung surfactant that is designed to provide the essential properties of human lung surfactant. Discovery believes that through its technology, pulmonary surfactants have the potential, for the first time, to be developed into a series of respiratory therapies for critical care and other hospitalized patients where there are few or no approved therapies available.

Discovery recently completed two Phase 3 clinical trials of Surfaxin[®], the Company's lead product, for the treatment of Respiratory Distress Syndrome in premature infants and is preparing to file new drug applications with the Food and Drug Administration and other regulatory authorities in the rest of the world. Discovery's Surfactant Replacement Therapy is also in a Phase 2 clinical trial for Acute Respiratory Distress Syndrome in adults and a Phase 3 and Phase 2 clinical trial for Meconium Aspiration Syndrome in full-term infants. Discovery recently completed a successful Phase 1b clinical trial and is currently preparing to initiate a follow-on Phase 2 clinical trial evaluating the safety, tolerability and efficacy of its humanized lung surfactant, delivered as an inhaled aerosol (development name DSC-104), to treat patients with asthma.

Historical Founding Transactions

The Company, formerly known as Ansan Pharmaceuticals, Inc. ("Ansan"), was incorporated in Delaware on November 6, 1992. In November 1997, Ansan merged with the predecessor company to the Company, Discovery Laboratories, Inc. ("Predecessor Discovery"), in a transaction accounted for as a reverse acquisition with Predecessor Discovery as the acquirer for financial reporting purposes. In October 1996, the Company invested in the stock of Acute Therapeutics, Inc., a Delaware corporation ("ATI"). Such investment represented 75% of the voting securities of ATI. At the time of the investment, ATI held the technology underlying the Company's proprietary humanized lung surfactant technology and employed or engaged the management developing such technology. Many of such management remain members of the Company's current management. In June 1998, ATI merged with and into the Company at which time, the Company's primary business objective was the development of the Company's proprietary humanized lung surfactant technology. The Company currently maintains one subsidiary, which is inactive.

Management's Plans and Financings

The Company was considered to be a development-stage company through December 31, 2002. With the completion of two Phase 3 clinical trials in 2003, the Company is no longer considered a development-stage enterprise. The Company has incurred substantial losses since inception. To date, the Company has funded its operations primarily through the issuance of equity and through strategic alliances. The Company expects to continue to expend substantial amounts for continued product research, development and commercialization activities for the foreseeable future. Management's plans with respect to funding this development are to secure additional equity, if possible, and to secure additional strategic alliances that will provide available cash funding for operations and to focus on increased commercialization efforts this year. Continuation of the Company is dependent on its ability to obtain additional financing and, ultimately, on its ability to achieve profitable operations. There is no assurance, however, that such financing will be available or that the Company's efforts ultimately will be successful.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Notes to Consolidated Financial Statements

December 31, 2003

Note 2 - Summary of Significant Accounting Policies**Cash and cash equivalents**

The Company considers all highly liquid investments purchased with a maturity of three months or less to be cash equivalents.

Available-for-sale marketable securities

The investments are classified as available for sale and are comprised of shares of high quality fixed income commercial paper and mutual funds. Investments are carried at fair market value. Realized gains and losses are computed using the average cost of securities sold. Any appreciation/depreciation on these investments is recorded as other comprehensive income (loss) in the statements of changes in stockholders' equity until realized.

Property and equipment

Property and equipment is recorded at cost. Depreciation of furniture and equipment is computed using the straight-line method over the estimated useful lives of the assets (five to seven years). Leasehold improvements are amortized over the lower of the (a) term of the lease or (b) useful life of the improvements.

Use of estimates

The preparation of financial statements, in conformity with accounting principles generally accepted in the United States, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Long-lived assets

Under Statement of Financial Accounting Standards (SFAS) No. 144, the Company is required to recognize an impairment loss only if the carrying amount of a long-lived asset is not recoverable from its undiscounted cash flows and measure any impairment loss as the difference between the carrying amount and the fair value of the asset. No impairment was recorded during the years ended December 31, 2003 and 2002, as management of the Company believes the sum of its future undiscounted cash flows will exceed the carrying amount of the assets.

Research and development

Research and development costs are charged to operations as incurred.

Revenue recognition – research and development collaborative agreements

The Company received nonrefundable fees from companies under license, sublicense, collaboration and research funding agreements. The Company initially records such funds as deferred revenue and recognizes research and development collaborative contract revenue when the amounts are earned, which occurs over a number of years as the Company performs research and development activities. See Note 7 – License, Research Funding and Commercialization Agreements for a detailed description of the Company's revenue recognition methodology under these agreements.

Additionally, the Company has been awarded grants from certain third party organizations to help fund research for the drugs that the Company is attempting to bring to full commercial use. Once

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Notes to Consolidated Financial Statements

December 31, 2003

research and development expenditures qualifying under the grant are incurred, grant reports are periodically completed and submitted to the granting agency for review. If approved, the granting agency will then remit payment to the Company. Such amounts are recorded as revenue upon receipt.

Stock-based compensation

The Financial Accounting Standards Board has issued Statement of Financial Accounting Standards ("SFAS") No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure". SFAS No. 148 amends SFAS No. 123, "Accounting for Stock-Based Compensation" to provide alternative methods of transition to a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS 123 to require prominent disclosure in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on the reported results. The Company continues to account for its stock option plans in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Options Issued to Employees" and, accordingly, recognizes compensation expense for the difference between the fair value of the underlying Common Stock and the exercise price of the option at the date of grant. The effect of applying SFAS No. 148 on pro forma net loss is not necessarily representative of the effects on reported net income or loss for future years due to, among other things, (i) the vesting period of the stock options and (ii) the fair value of additional stock options in future years. Had compensation cost for the Company's stock option plans been determined based upon the fair value of the options at the grant date of awards under the plans consistent with the methodology prescribed under SFAS No. 148, the pro forma net loss for the years ended December 31, 2003, 2002, and 2001 would have been as follows:

	Years Ended December 31,		
	2003	2002	2001
Net Loss as reported	\$ (24,280,000)	\$ (17,443,000)	\$ (11,146,000)
Additional stock-based employee compensation	\$ (3,738,000)	\$ (2,264,000)	\$ (2,090,000)
Pro forma net loss	<u>\$ (28,018,000)</u>	<u>\$ (19,707,000)</u>	<u>\$ (13,236,000)</u>
Pro forma net loss per share	\$ (0.75)	\$ (0.72)	\$ (0.60)

The weighted average fair value of the options granted were estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	Years Ended December 31,		
	2003	2002	2001
Expected dividend yield	0%	0%	0%
Expected stock price volatility	86%	95%	118%
Risk-free interest rate	2.4%	2.5%	4%
Expected option term	3.5 years	3.5 years	3.5 years

Net loss per common share

Net loss per common share is computed pursuant to the provisions of SFAS No. 128, "Earnings per Share", and is based on the weighted average number of common shares outstanding for the periods. For the years ended December 31, 2003, 2002, and 2001, 8,753,000, 4,032,000 and

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Notes to Consolidated Financial Statements

December 31, 2003

5,211,000 common shares, respectively, are potentially issuable upon the exercise of certain of the Company's stock options and warrants and are not included in the calculation of net loss per share as the effect would be anti-dilutive.

Reclassification

Certain prior year balances have been reclassified to conform with the current presentation.

Note 3 – Investments

The available-for-sale marketable securities are as follows:

	December 31,	
	2002	2001
Cost	\$10,475,000	\$ 12,866,000
Gross unrealized gain	178,000	131,000
Gross unrealized loss	(1,000)	(59,000)
Estimated fair value	<u>\$ 10,652,000</u>	<u>\$ 12,938,000</u>

Included in the net loss for the years ended December 31, 2003, 2002, and 2001 were gross realized gains on available-for-sale securities of \$114,000, \$183,000 and \$219,000 and gross realized losses of \$0, \$9,000 and \$274,000, respectively.

Note 4 – Note Receivable

Note receivable pertains to a \$200,000, 7% per annum mortgagor's note due from an executive of the Company. This note is secured by a mortgage agreement dated July 24, 2001. The note calls for monthly payments of principal and interest over a 360-month period. The principal balance outstanding at December 31, 2003 and 2002 was approximately \$195,000 and \$197,000, respectively.

Note 5 - Property and Equipment

Property and equipment as of December 31, 2003 and 2002 was comprised of the following:

	December 31,	
	2003	2002
Leasehold Improvements	\$ 174,000	\$ 144,000
Furniture	314,000	239,000
Equipment	2,217,000	1,600,000
Construction in Progress	792,000	—
	<u>3,497,000</u>	<u>1,983,000</u>
Accumulated Depreciation	<u>(1,083,000)</u>	<u>(752,000)</u>
	<u>\$ 2,414,000</u>	<u>\$1,231,000</u>

Depreciation expense for the years ended December 31, 2003, 2002, and 2001 was \$331,000, \$252,000, and \$184,000, respectively.

The equipment balance at December 31, 2003 and 2002 includes \$1,468,000 and \$559,000, respectively, of property subject to a capital lease. The related accumulated depreciation was \$194,000 and \$57,000 at December 31, 2003 and 2002, respectively.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Notes to Consolidated Financial Statements

December 31, 2003

The balance of Construction in Progress primarily consists of new manufacturing equipment related to the enhancement of our manufacturing capabilities for Surfaxin. As of December 31, 2003 and 2002, the Company had additional construction commitments outstanding totaling approximately \$554,000 and \$188,000, respectively.

Note 6 - Income Taxes

Since its inception, the Company has never recorded a provision or benefit for Federal and state income taxes.

The reconciliation of the income tax benefit computed at the Federal statutory rates to the Company's recorded tax benefit for the years ended December 31, 2003, 2002, and 2001 are as follows:

	December 31,		
	2003	2002	2001
Income tax benefit, statutory rates	\$ 8,255,000	\$ 5,938,000	\$ 3,783,000
State taxes on income, net of federal benefit	2,015,000	1,088,000	698,000
Research and development tax credit	441,000	274,000	90,000
Other	92,000	(755,000)	3,000
Income tax benefit	10,803,000	6,545,000	4,574,000
Valuation allowance	(10,803,000)	(6,545,000)	(4,574,000)
Income tax benefit	\$ —	\$ —	\$ —

The tax effects of temporary differences that give rise to deferred tax assets and deferred tax liabilities, at December 31, 2003 and 2002, are as follows:

	December 31,	
	2003	2002
Long-term deferred tax assets:		
Net operating loss carryforwards (federal and state)	\$ 35,607,000	\$ 25,526,000
Research and development tax credits	1,868,000	1,225,000
Other Accrued	70,000	—
Deferred Revenue	273,000	—
Capitalized research and development	122,000	222,000
Total long-term deferred tax assets	37,940,000	26,973,000
Long-term deferred tax liabilities:		
Property and equipment	(272,000)	(108,000)
Net deferred tax assets	37,668,000	26,865,000
Less: valuation allowance	(37,668,000)	(26,865,000)
	\$ —	\$ —

The Company was in a net deferred tax asset position at December 31, 2003 and 2002 before the consideration of a valuation allowance. Due to the fact that the Company has never realized a profit, management has fully reserved the net deferred tax asset since realization is not assured.

At December 31, 2003 and 2002, the Company had available carryforward net operating losses for Federal tax purposes of approximately \$91,585,000 and \$65,112,000, respectively, and a research and development tax credit carryforward of \$1,868,000 and \$1,225,000, respectively. The Federal net

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Notes to Consolidated Financial Statements

December 31, 2003

operating loss and research and development tax credit carryforwards expire beginning in 2009 and continuing through 2022. At December 31, 2003, the Company had available carryforward net operating losses of \$893,000 related to stock based compensation. Additionally, at December 31, 2003 and 2002, the Company had available carryforward losses of approximately \$82,483,000 and \$51,385,000, respectively, for state tax purposes. The utilization of the Federal net operating loss carryforwards is subject to annual limitations in accordance with Section 382 of the Internal Revenue Code. Certain state carryforward net operating losses are also subject to annual limitations.

The difference between the accumulated deficit for financial reporting purposes and the net operating loss carryforwards for tax purposes is primarily due to the write-off of the acquired in-process research and development and supplies, which is not deductible for tax purposes and disallows deductions for research and development expenditures for which the Company has received a tax credit.

Note 7 - License, Research Funding, and Commercialization Agreements

In March 2002, the Company expanded its existing alliance with Esteve to develop, market and sell Surfaxin within Central and South America, Mexico and Southern Europe. In connection with this new Esteve collaboration, Esteve purchased 821,862 shares of Common Stock for an aggregate consideration of \$4 million (at a 50% premium over the average closing price for the 30 days prior to the closing date) and paid the Company a non-refundable licensing fee of \$500,000. Esteve agreed to provide certain commercialization services for Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants and Acute Lung Injury/Acute Respiratory Distress Syndrome in adult patients. The Company has agreed to an exclusive supply agreement which provides that Esteve will purchase from the Company all of its Surfaxin drug product requirements at an established transfer price based on sales of Surfaxin by Esteve and/or its sublicensee(s). Esteve has also agreed to sponsor certain clinical trial costs related to obtaining regulatory approval in Europe for indications in Acute Lung Injury/Acute Respiratory Distress Syndrome. Further, Esteve also agreed to make certain milestone payments to the Company upon the attainment of European marketing regulatory approval of Surfaxin.

The Company has accounted for the license fees associated with this new Esteve collaboration and the Esteve collaboration entered into in October 1999 (including the premium paid for Common Stock), the reimbursement of research and development expenditures, and the advance payment for Surfaxin received from Esteve to be used in clinical trials as deferred revenue. The balance in deferred revenue at December 31, 2003 relates entirely to the license agreement with Esteve for which the Company will recognize revenue using a straight line method through the anticipated date of FDA approval for the first Surfaxin neonatal indication.

On December 10, 2001, the Company entered into a collaboration arrangement with Quintiles, and its affiliate, PharmaBio Development, Inc. ("PharmaBio"), whereby Quintiles will provide pre- and post-launch marketing services for the commercialization of Surfaxin for Respiratory Distress Syndrome in premature infants and/or Meconium Aspiration Syndrome in full-term infants in the United States. In connection therewith, the Company issued to PharmaBio for aggregate consideration of \$3 million: (i) 791,905 shares of Common Stock; (ii) Class G warrants to purchase 357,143 shares of Common Stock at an exercise price equal to \$3.485 per share; and (iii) Class H warrants to purchase 320,000 shares of Common Stock at an exercise price equal to \$3.03 per share.

PharmaBio also committed to provide the Company with a secured revolving credit facility (the "Credit Facility"), primarily for use to pay pre-launch marketing services to be provided by Quintiles, subject to the Company satisfying certain conditions, for up to \$8.5 million, which may be increased to \$10 million in specified circumstances. To the extent the Credit Facility availability is increased to greater than \$8.5 million, for each \$1 million dollar increase, the amount of shares of Common Stock issuable pursuant to the Class H warrants will be increased by approximately 38,000 shares. Principal amounts owed under

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Notes to Consolidated Financial Statements
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the Credit Facility may be paid out of the proceeds of milestone payments to be paid by PharmaBio to the Company at certain intervals upon the achievement of certain corporate milestones by the Company. At December 31, 2003 and 2002, \$2,436,000 and \$1,450,000, respectively, was outstanding under the Credit Facility.

The Company and Ortho Pharmaceuticals, Inc. ("Ortho Pharmaceuticals"), a wholly-owned subsidiary of Johnson & Johnson, Inc., are parties to an agreement granting an exclusive license of the Surfaxin technology to the Company in exchange for certain license fees, future milestone payments (aggregating \$2,750,000) and royalties.

The Company and The Scripps Research Institute ("Scripps") are parties to a research funding and option agreement which expires in February 2005, subject to termination by the Company at any time with 90 days prior notice. Pursuant to this agreement, the Company is obligated to fund a portion of Scripps' research efforts and thereby has the option to acquire an exclusive worldwide license to the technology developed from the research program during the term of the agreement. Scripps owns all of the technology that it developed pursuant to work performed under the agreement. To the extent the Company does not exercise its option to technology developed under the agreement, the Company has the right to receive 50% of the net royalty income received by Scripps for inventions that are jointly developed under the agreement. Payments to Scripps under this agreement were \$649,000, \$572,000 and \$508,000 in 2003, 2002, and 2001, respectively.

Note 8 - Stockholders' Equity

2003 Shelf Registration Statement

On December 19, 2003, the Company filed a Form S-3 shelf registration statement with the Securities and Exchange Commission ("SEC") for the proposed offering from time to time of up to 6,500,000 shares of its Common Stock. The Company has no immediate plans to sell its securities under the shelf registration, however, since the registration statement has been declared effective by the SEC, the Company will be able to issue the securities from time to time in response to market conditions or other circumstances on terms and conditions that will be determined at such time.

2003 private placement

In June 2003, the Company completed the sale of securities in a private placement to selected institutional and accredited investors for net proceeds of approximately \$25.9 million. The Company issued 4,997,882 shares of Common Stock and 999,577 Class A Investor warrants to purchase shares of Common Stock at an exercise price of \$6.875 per share. The Class A Investor warrants have a seven-year term. As of December 31, 2003, approximately 955,000 of the Class A Investor warrants remain unexercised.

2002 private placement

In November 2002, the Company received approximately \$11.9 million in net proceeds from the sale of 6,397,517 shares of Common Stock and 2,878,883 Class I warrants to purchase shares of Common Stock at an exercise price of \$2.425 per share. The Class I warrants are exercisable through November 5, 2007. In connection with this private placement, the placement agent received fees of approximately \$766,000. All of the Class I warrants have been exercised.

2001 private placements

In October 2001, the Company received approximately \$7.3 million in net proceeds from the sale of 3,562,759 shares of Common Stock and 712,553 Class F warrants to purchase shares of Common Stock at an exercise price of \$2.365 per share. The Class F warrants are exercisable through September 30,

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

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2006. In connection with this private placement, the placement agent received fees of approximately \$360,000 and warrants to purchase 164,911 shares of Common Stock at \$2.394 per share. All of the Class F warrants have been exercised.

In April 2001, the Company received approximately \$1 million in proceeds in a private placement sale of 296,560 shares of Common Stock to a limited partnership.

Common shares reserved for issuance

As of December 31, 2003 and 2002, the Company has reserved shares of Common Stock for issuance as follows:

	December 31,	
	2003	2002
Stock option plans	5,587,000	4,908,000
401(k) discretionary match	129,000	—
2003 Shelf Registration Statement	6,500,000	—
Placement agent and underwriter warrants	1,017,000	1,610,000
Class C warrants (1999 private placement)	—	57,000
Class E warrants (2000 private placement)	549,000	581,000
Class F warrants (2001 private placement)	—	713,000
Class G warrants (2001 Quintiles Alliance)	357,000	357,000
Class H warrants (2001 Quintiles Credit Facility)	565,000	565,000
Class I warrants (2002 private placement)	—	2,879,000
Class A warrants (2003 private placement)	955,000	—
Other warrants	—	75,000
	16,659,000	11,745,000

Treasury stock/Common Stock issued for services

The Company has a stock repurchase program wherein the Company may buy its own shares on the open market and use such shares to settle indebtedness. Such shares are accounted for as treasury stock.

During 2003, the Company acquired 128,936 shares of Common Stock for approximately \$1,050,000 from a related party in payment for the exercise of certain stock options available to the related party. Such shares are accounted for as treasury stock.

During 2002, the Company did not acquire, nor did it issue any Common Stock accounted for as treasury stock.

During 2001, the Company acquired 11,500 shares of Common Stock for approximately \$26,000. Such shares are accounted for as treasury stock. In addition, during 2001, the Company issued 10,902 shares of Common Stock in lieu of cash payments for services and rent.

Note 9 - Stock Options

In March 1998, the Company adopted its 1998 Stock Incentive Plan, which includes three equity programs (the "1998 Plan"). Under the Discretionary Option Grant Program, options to acquire shares of the Common Stock may be granted to eligible persons who are employees, non-employee directors, consultants and other independent advisors. Pursuant to the Stock Issuance Program, such eligible

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

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December 31, 2003

persons may be issued shares of the Common Stock. Under the Automatic Option Grant Program, eligible non-employee directors will automatically receive option grants at periodic intervals at an exercise price equal to the fair market value per share on the date of the grant. Options granted under the 1998 Plan expire no later than 10 years from the date of the grant.

The 1998 Plan was successively amended at each of the Annual Meeting of Stockholders for the years 2003, 2002, and 2001, to increase the maximum number of shares of Common Stock reserved for issuance over the term of the plan by 1,420,000 shares, 1,000,000 shares and 1,150,000 shares, respectively. After giving effect to these amendments, there are currently 6,570,000 shares of Common Stock reserved for issuance over the term of the plan. In addition, in 2002 the Board of Directors approved amendments to the 1998 Plan that (i) increased the exercise price of options granted to non-employee directors pursuant to the Automatic Option Grant Program from 60% to 100% of the fair market value per share on the date of the grant and (ii) removed the Plan Administrator's authority to effect the cancellation and regrant of any outstanding options under the Discretionary Option Grant Program.

A summary of the Company's stock option activity and related information is as follows:

	Price Per Share	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Balance at January 1, 2001	\$0.0026 – \$7.00	3,106,166	\$3.42	8.37 years
Options granted	2.10 - 5.25	1,255,000	2.55	
Options exercised	0.3205 - 0.87	(6,224)	0.47	
Options forfeited	2.10 - 5.19	(107,983)	4.13	
Balance at December 31, 2001	0.0026 - 7.00	4,246,959	3.15	8.01 years
Options granted	1.26 - 3.65	1,786,000	2.14	
Options exercised	0.0821 - 2.10	(77,925)	0.77	
Options forfeited	.3205 - 7.00	(349,850)	3.34	
Balance at December 31, 2002	0.0026 - 5.375	5,605,184	2.85	7.81 years
Options granted	1.70 - 9.17	1,111,750	6.75	
Options exercised	0.0026 - 4.22	(993,001)	1.95	
Options forfeited	0.1923 – 5.06	(168,611)	2.76	
Balance at December 31, 2003	0.0026 – 9.17	5,555,322	3.80	7.44 years

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Notes to Consolidated Financial Statements

December 31, 2003

The following table provides further detail with regard to the options outstanding and exercisable at December 31, 2003:

Price per share	Shares	Weighted Average Price per Share	Weighted Average Remaining Contractual Life
\$0.0026 - \$2.00	1,120,910	\$1.56	7.60 years
\$2.01 - \$4.00	2,029,614	\$2.67	7.64 years
\$4.00 - \$6.00	1,545,798	\$4.62	5.82 years
\$6.01 - \$8.00	205,000	\$7.28	9.65 years
\$8.01 - \$10.00	654,000	\$8.09	9.70 years

The following table pertains to options granted and exercisable at less than fair value:

	2003	December 31, 2002	2001
Weighted average exercise price	\$2.09	\$2.00	\$2.11
Weighted average fair value	\$3.49	\$3.33	\$3.53

Included in the options outstanding, are options to purchase 117,200 shares of Common Stock (at an exercise price of \$4.44) granted during 1998, which vest upon the Company achieving specified milestones and expire in June 2008. In December 2002, the related milestones were achieved.

In December 2002, the Board of Directors approved the issuance of options to management to purchase up to 800,000 shares of Common Stock at an exercise price of \$2.75 per share. Such options had been subject to the approval of the Company's shareholders, which was obtained at the time of the Company's Annual Meeting of Shareholders for 2003. Accordingly, such options are now included in the options outstanding at December 31, 2002. Such options shall vest in their entirety upon the fourth anniversary of the date of grant or at such earlier time, if ever, upon the receipt by the Company of a New Drug Application (NDA) approval by the United States Food and Drug Administration for Surfaxin for either Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants, or Acute Respiratory Distress Syndrome in adults.

In December 2003, the Board of Directors approved the issuance of options to management to purchase up to 1,464,500 shares of Common Stock at an exercise price of \$9.17 per share. Such options are expressly subject to the requisite approval of the Company's shareholders, to be obtained no later than the Company's Annual Meeting of Shareholders for 2004, for an amendment to the 1998 Plan authorizing an increase in the number of shares issuable under the plan in an amount equal to or greater than the aggregate amount of such options. Accordingly, such options are not included in the options outstanding at December 31, 2003. Provided the shareholders of the Company approve such amendment, such options shall vest over a three year period from the date of the grant.

Note 10 – 401(k) Match

The Company has a voluntary 401(k) savings plan covering eligible employees. Effective January 1, 2003, the Company allows for periodic discretionary matches as a percentage of each participant's contributions in newly issued Company stock. The total match for the year ending December 31, 2003 was \$119,000.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Notes to Consolidated Financial Statements

December 31, 2003

Note 11 – Commitments

The Company's long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business.

Payments due under contractual obligations at December 31, 2003 are as follows:

	2004	2005	2006	2007	Total
Credit facility with corporate partner ⁽¹⁾	2,436,000	—	—	—	2,436,000
Capital lease obligations ⁽²⁾	473,000	425,000	238,000	131,000	1,267,000
Operating lease obligations ⁽³⁾	530,000	291,000	28,000	—	849,000
Purchase obligations ⁽⁴⁾	554,000	—	—	—	554,000
Employment agreements ⁽¹⁾	1,820,000	1,567,000	—	—	3,387,000
Total	5,813,000	2,283,000	266,000	131,000	8,493,000

(1) See further discussion below.

(2) Capital leases obligations primarily relate to a capital lease financing arrangement with General Electric Capital Corporation discussed below.

(3) Operating lease obligations include property rental agreements discussed below.

(4) Purchase obligations include commitments of equipment and services for the enhancement of our manufacturing capabilities for Surfaxin.

In addition to the contractual obligations above, the Company has future milestone commitments, aggregating \$2,750,000, and royalty obligations to Ortho Pharmaceuticals, a wholly-owned subsidiary of Johnson & Johnson, Inc., related to the Company's product licenses.

The Company has a secured revolving credit facility of up to \$8.5 to \$10 million with PharmaBio to fund pre-marketing activities for a Surfaxin launch in the United States. The credit facility is available for use until December 10, 2004, and monies become available in three tranches upon satisfying certain conditions. The Company has satisfied the conditions for availability of the first two tranches and at December 31, 2003, the amount available under the credit facility was approximately \$5.7 million, of which \$2.4 million was outstanding. Interest on amounts advanced under the credit facility will be payable quarterly in arrears. Outstanding principal and interest due under the credit facility are due and payable on December 10, 2004. Although the Company may be able to repay principal amounts owed under the credit facility from proceeds of milestone payments to be paid by PharmaBio upon the achievement of certain corporate milestones, there can be no assurance that the Company will achieve any of these milestones prior to the repayment date, and doing so is not likely unless the FDA expedites the review of the NDA for Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants that the Company expects to file with the FDA in April 2004, and approves such NDA prior to December 10, 2004. The Company is obligated to use a significant portion of the funds borrowed under the credit facility for pre-launch marketing services to be provided by Quintiles.

The Company has a capital lease financing arrangement with the Life Science and Technology Finance Division of General Electric Capital Corporation that provides, subject to certain conditions, for up to \$1 million in financing for capital purchases. In 2003, the arrangement was increased to provide, subject to certain conditions, up to an aggregate \$4 million in financing for capital purchases. As of December 31, 2003, approximately \$962,000 was outstanding under this financing arrangement.

At December 31, 2003, the Company had employment agreements with six officers providing for an aggregate annual salary of \$1,567,000. The agreements expire in December 2005, however, commencing on January 1, 2006, and on each January 1st thereafter, the term of these agreements shall automatically be extended for one additional year, unless at least 90 days prior to such January 1st date,

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

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the Company or the Executive shall have given notice that it does not wish to extend the agreement. The Company also had employment agreements with two other executives that provide for an aggregate annual salary of \$340,000, which expire in June and November 2004. All of the foregoing agreements provide for the issuance of annual bonuses and the granting of options subject to approval by the Board of Directors.

At December 31, 2003, the Company leased office and laboratory space in Doylestown, Pennsylvania under leases which expire in September 2004, March 2005 and September 2005. Additionally, the Company leased office and laboratory space in Redwood City, California under a lease that expires February 2006 and office space in Windsor, United Kingdom under a lease, which expired December 2003. Payments made under these leases for the years ended December 31, 2003, 2002, and 2001 were \$590,000, \$481,000 and \$273,000 respectively.

Aggregate future minimum annual rents for these leases are as follows:

2004	\$	530,000
2005		291,000
2006		28,000
	<u>\$</u>	<u>849,000</u>

The Company entered into agreements to lease manufacturing, laboratory and office equipment, which are being accounted for as capital leases. Future minimum lease payments for these leases are as follows:

2004	473,000
2005	425,000
2006	238,000
2007	131,000
	<u>1,267,000</u>
Less amounts representing interest	<u>(173,000)</u>
	<u>\$ 1,094,000</u>

Note 12 - Related Party Transactions

In November 2001, the Company entered into an agreement with Clinical Data Management, Inc. (CDM), replacing an earlier similar agreement, to perform duties associated with processing data for the Company's ongoing clinical trials. Such agreement expired on November 14, 2002 pursuant to its terms and the Company has not entered into any further arrangements with CDM. CDM is wholly-owned by the spouse of the Company's President and Chief Executive Officer. Payments made to CDM and its owner for the years ended December 31, 2002 and 2001 were approximately \$289,000, \$221,000 respectively. There were no such payments made in 2003.

In March 2002, the Company expanded its existing relationship with Esteve by entering into an agreement to expand the territory covered by the collaboration arrangement entered into with Esteve in October 1999. Pursuant to this agreement, Esteve purchased 821,862 shares of the company's Common Stock at \$4.867 per share for \$4 million in cash and paid a non-refundable licensing fee of \$500,000. A member of the Company's board of directors is an executive officer of Esteve.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

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Note 13 – Selected Quarterly Financial Data (unaudited)

The following table contains unaudited statement of operations information for each quarter of 2003 and 2002. The operating results for any quarter are not necessarily indicative of results for any future period.

2003 Quarters Ended:		<i>(in thousands, except per share data)</i>				
	Mar. 31	June 30	Sept. 30	Dec. 31	Total Year	
Revenues from collaborative agreements	\$ 393	\$ 263	\$ 198	\$ 183	\$ 1,037	
Operating Expenses:						
Research and development	3,844	4,011	5,096	6,799	19,750	
General and administrative	1,167	1,137	1,375	2,043	5,722	
Total expenses	5,011	5,148	6,471	8,842	25,472	
Operating loss	(4,618)	(4,885)	(6,273)	(8,659)	(24,435)	
Other income and expense	113	36	54	(48)	155	
Net loss	\$ (4,505)	\$ (4,849)	\$ (6,219)	\$ (8,707)	\$ (24,280)	
Net loss per common share - basic and diluted	\$ (0.14)	\$ (0.14)	\$ (0.15)	\$ (0.21)	\$ (0.65)	
Weighted average number of common shares outstanding	32,857	33,487	41,084	42,391	37,426	
2002 Quarters Ended:		<i>(in thousands, except per share data)</i>				
	Mar. 31	June 30	Sept. 30	Dec. 31	Total Year	
Revenues from collaborative agreements	\$ 237	\$ 783	\$ 368	\$ 394	\$ 1,782	
Operating Expenses:						
Research and development	2,605	3,721	3,475	4,546	14,347	
General and administrative	1,132	1,538	1,633	1,155	5,458	
Total expenses	3,737	5,259	5,108	5,701	19,805	
Operating loss	(3,500)	(4,476)	(4,740)	(5,307)	(18,023)	
Other income and expense	130	189	211	50	580	
Net loss	\$ (3,370)	\$ (4,287)	\$ (4,529)	\$ (5,257)	\$ (17,443)	
Net loss per common share - basic and diluted	\$ (0.13)	\$ (0.16)	\$ (0.17)	\$ (0.17)	\$ (0.64)	
Weighted average number of common shares outstanding	25,834	26,394	26,441	30,717	27,351	

Discovery Executive Management

Robert J. Capetola, Ph.D.
President and Chief Executive Officer

John G. Cooper
*Executive Vice President and
Chief Financial Officer*

David L. Lopez, CPA, Esq.
Senior Vice President, General Counsel

Ralph Niven, Ph.D., M.R.Pharm.S.
*Senior Vice President,
Preclinical Development*

Christopher J. Schaber, Ph.D.
*Executive Vice President and
Chief Operating Officer*

Robert Segal, M.D., F.A.C.P.
*Senior Vice President, Clinical Research
and Chief Medical Officer*

Huei Tsai, Ph.D.
Senior Vice President, Biometrics

Deni M. Zodda, Ph.D.
*Senior Vice President,
Business Development*

Board of Directors

Herbert H. McDade, Jr. (Chairman)
*Chairman, Access Pharmaceuticals, Inc.
Former President of Revlon Health Care
and Armour Pharmaceutical Company*

Robert J. Capetola, Ph.D.
*President and Chief Executive Officer,
Discovery Laboratories, Inc.*

Antonio Esteve, Ph.D.
*Member Executive Committee and
Director Scientific and Commercial
Operations, Laboratorios del Dr. Esteve*

Max Link, Ph.D.
*Chairman, Centerpulse, Ltd.
Former Chief Executive Officer of
Sandoz Pharma, Ltd.*

Marvin E. Rosenthale, Ph.D.
*Former President and Chief
Executive Officer of Allergan
Ligand Retinoid Therapeutics, Inc.*

Selected Scientific Advisors

Charles G. Cochran, M.D.
*Founder and Professor of Immunology
The Scripps Research Institute*

Steven M. Donn, M.D.
*Professor of Pediatrics
Director, Neonatal-Perinatal Medicine
University of Michigan Health System*

R. Duncan Hite, M.D., FCCP
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Director of Medical Intensive Care
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Wake Forest University School of Medicine*

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Professor of Medicine
University of Washington School of Medicine*

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Annual Meeting of Shareholders

*Tuesday, May 11, 2004
New York Athletic Club
180 Central Park South
New York, NY*

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When used in this report, the words "believes," "anticipates," "expects," "intends," "may" and similar expressions are intended to identify forward-looking statements. There are a number of important factors that could cause the Company's actual results to differ materially from those indicated by the forward-looking statements, which speak only as of the date made. The Company undertakes no obligation to republish revised forward-looking statements to reflect subsequent events or circumstances or to reflect the occurrence of unanticipated events. Readers are also urged to review carefully and consider the various disclosures made by the Company that attempt to advise interested parties of the factors that affect the Company's business, including this report, as well as the Company's periodic filings with the SEC including the most recent reports on Form 10-K, 8-K and 10-Q, and amendments thereto.

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